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HACCP
Advantage

Guidebook

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The HACCP Advantage Guidebook

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THE HACCP ADVANTAGE

Guidebook

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CHAPTER ONE

Introduction

Key Points in Chapter 1

The *HACCP Advantage Guidebook* is an interpretive guide to the *HACCP Advantage Program Manual* and can be used by anyone when designing and implementing a *HACCP Advantage* system.

The *HACCP Advantage* is specifically designed for small to medium-sized businesses.

Introduction

1. PURPOSE OF THE GUIDEBOOK

This guidebook is intended to be a companion and interpretative guide to the *HACCP Advantage Program Manual*. The Program Manual details the requirements of the *HACCP Advantage* program, and this guidebook provides practical assistance to implement those requirements.

The prerequisite program standards and HACCP plans could be implemented without this book; however, it will prove a valuable aid in system development and implementation. The information and examples presented are specific to the program and will help you understand its requirements.

The book begins with a basic explanation of HACCP and the components of the *HACCP Advantage*, then takes you through the main steps of system development, implementation, maintenance and certification. Sample forms and checklists are provided. Using the principles and concepts introduced, you can develop and implement a HACCP system specific to your facility.

In addition to the information provided here, you will need an adequate understanding of food safety principles and the hazards associated with the products you produce.

2. WHO SHOULD USE THIS GUIDEBOOK?

The *HACCP Advantage* has been designed to be feasible and practical for non-federally registered food processors, regardless of size or commodity. The *HACCP Advantage* can be implemented at either end of the food chain, including by on-farm processors.

This book will be useful for a variety of people involved in HACCP including:
- HACCP co-ordinators
- HACCP team members
- Plant management
- Production supervisors
- HACCP and food safety consultants
- Anyone interested in HACCP.

3. ICONS USED IN THIS BOOK

To help make this book more useful and to help you implement the *HACCP Advantage*, we have included a few extra features.

---

makingthe**grade**

To gain certification for your HACCP system, you will need to achieve a successful audit. We have included audit–related tips and steps in these boxes.

---

technical**terms**

We've explained terms that may be unfamiliar to you in these boxes. You will also find a glossary of terms and definitions at the back of the book.

---

didyou**know**

These boxes provide interesting tidbits of information to share with colleagues.

CHAPTERTWO

HACCP Explained

Key Points in Chapter 2

HACCP is a preventative food safety system that helps ensure the manufacturing of safe food products.

Most HACCP programs include prerequisite programs and HACCP plans.

HACCP systems control three types of hazards: biological, chemical and physical.

HACCP systems can provide food processing operations with a number of benefits, including increased market access.

CHAPTER TWO

HACCP Explained

1. WHAT IS HACCP?

HACCP stands for **H**azard **A**nalysis and **C**ritical **C**ontrol **P**oint

HACCP is an internationally recognized, science-based, food safety system that is used to help ensure the manufacture of safe food products.

HACCP is designed to prevent, reduce or eliminate potential biological, chemical and physical food safety hazards, including those caused by cross-contamination.

During the development of a HACCP system, potential hazards are identified and control measures are implemented at specific points in the manufacturing process.

HACCP:

- Provides a more systematic approach to ensuring food safety than traditional inspection procedures
- Places more responsibility for ensuring food safety on the food manufacturer than traditional inspection programs
- Is based on science, rather than simply past experience or subjective judgement
- Focuses on preventing problems before they occur, rather than trying to detect failures through end-product testing.

HACCP is internationally recognized as the primary means for enhancing food safety throughout the food chain, and is increasingly being used around the world.

A HACCP system is the responsibility of the company. The food manufacturer has the most control over the product and thus can have the greatest impact on the safety of the food produced. Government authorities may provide recognition of HACCP systems, but the actual development, implementation and maintenance is up the manufacturer.

didyou**know**

HACCP is currently being used in many jurisdictions around the world. For example, HACCP can be found in Canada, Australia, Cuba, the European Union, Iceland, Japan, Malaysia, New Zealand, the United States, and many other countries.

didyou**know**

HACCP was originally developed in the 1960s by the Pillsbury Company, the National Aeronautics & Space Administration (NASA), and the United States Army Laboratories to ensure the safety of the food supply for astronauts while in space.

technical**terms**

A HACCP **system** is specific to a food processing operation within a facility. A HACCP **program** consists of the standards and requirements defined by a recognition body (for example, the *HACCP Advantage* program).

didyou**know**

In Canada, the Canadian Food Inspection Agency has two HACCP programs under its jurisdiction, the *Food Safety Enhancement Program* (FSEP) and the *Quality Management Program (QMP)*. The United States Department of Agriculture has HACCP requirements in the *Final Rule on Pathogen Reduction and Hazard Analysis* and *Critical Control Point (HACCP) Systems.*

A. The Codex Alimentarius Commission and HACCP

HACCP methodology has been standardized internationally by the Codex Alimentarius Commission. The *HACCP Advantage* is based upon the guidelines and principles set out by this commission.

The information provided by Codex is used around the world in the development of HACCP programs (e.g., the *HACCP Advantage* and the *Food Safety Enhancement Program*); however, each approach developed may be somewhat different. For instance, a government may choose to build regulatory or trade requirements into an approach, or set prescriptive standards rather than outcome-based standards.

B. The Components of a HACCP System

There are two components of an effective HACCP system:

1. **Prerequisite Programs**—Designed to control hazards related to *personnel* and the food manufacturing *environment*, creating conditions that are favourable to the production of safe food products.

2. **HACCP Plans**—Designed to control hazards directly related to the *food* being processed or the manufacturing *process*.

HACCP System = Prerequisite Programs + HACCP Plan(s)

i. Prerequisite Programs

Prerequisite programs are designed to ensure a suitable and safe environment for food manufacturing that does not present sources of contamination. To control and prevent hazards within the manufacturing environment:

- Appropriate personal practices are managed
- Shipping, receiving and storage practices are managed
- Equipment and structures are maintained
- Water supply safety is maintained
- Sanitation and pest control activities are performed
- Appropriate employee training is provided

Prerequisite programs encompass universal criteria that must be controlled regardless of the product being manufactured. However, there may be elements of the prerequisite programs that focus on characteristics inherent to the product or manufacturing process. For instance, the sanitation program must include procedures that are specific for the equipment that is used within the facility.

Prerequisite programs are implemented prior to the HACCP plan(s) because they control a large number of general hazards that then do not need to be controlled in a HACCP plan, thereby making the system more efficient and easier to maintain. Prerequisite programs lay the foundation for effective HACCP plans.

ii. HACCP Plans

A HACCP plan is designed to control hazards directly related to the product, ingredients or manufacturing process that are not controlled by the prerequisite programs. HACCP plans are developed through a process of hazard analysis to determine hazards significant to food safety. Control measures are then put into place to prevent, reduce or eliminate these hazards. The control measures are monitored for effectiveness. If a hazard is not adequately controlled (the control measure fails), actions are taken to correct the failure.

didyou**know**

The Codex Alimentarius Commission was created by the Food and Agricultural Organization (FAO) and the World Health Organization (WHO) of the United Nations to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. In an effort to eliminate problems associated with differing interpretations of how HACCP should be applied, the Codex Alimentarius Commission produced internationally agreed-upon HACCP guidelines. The information provided by Codex Alimentarius is used around the world in the development of HACCP approaches.

HACCP PRINCIPLES

HACCP Plans are developed using seven principles standardized by the Codex Alimentarius Commission.

Principle 1: Conduct a hazard analysis

Conducting a *hazard analysis* is the process of identifying the hazards that might affect a particular product in a specific processing operation, and then collecting and evaluating information on the hazards and conditions leading to their presence to decide which are significant to food safety and must be addressed in the HACCP plan.

Principle 2: Determine the Critical Control Points

A *critical control point* (CCP) is a point, step or procedure in a food manufacturing process at which a control measure can be applied and is essential to prevent, eliminate or reduce a food safety hazard to an acceptable level. Determining the CCPs involves identifying where in the processing operation the hazards addressed in the HACCP plan can be prevented, reduced or eliminated.

Principle 3: Establish critical limits

Critical limits are criteria that separate safe product from unsafe product. Critical limits must be established for each CCP. Critical limits must be clearly defined and measurable.

Principle 4: Establish monitoring procedures

Monitoring is the process of conducting a planned sequence of observations or measurements to determine if a CCP is under control. For each CCP, monitoring procedures must be implemented and documented to ensure that the critical limit is being met.

Principle 5: Establish corrective actions

Corrective actions are predetermined activities that are taken when CCP monitoring results indicate that a deviation has occurred and there is the potential that unsafe food has been, or will be, produced. For each CCP there must be planned, written corrective actions. The objectives of taking corrective actions are to regain control of the hazard, to determine the disposition of the affected product and to prevent a reoccurrence of the problem.

Principle 6: Establish verification procedures

Verification is the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine conformance with the HACCP plan. Verification confirms that the HACCP plan is operating effectively and according to written procedures.

Principle 7: Establish record-keeping and documentation procedures

HACCP plans, including all of the items listed above, must be documented. The required monitoring and verification records must be complete and accurate.

C. Types of Food Hazards Controlled by HACCP

For the purposes of HACCP, hazards refer to agents in or conditions of food that can cause illness, injury or death of a person. These hazards fall into three categories: biological, chemical and physical.

i. Biological Hazards

Biological hazards are those caused by micro-organisms. There are four general categories of biological hazards:

a. Bacteria

When present in food, bacteria can cause illness in humans either through infection or intoxication. Ingesting bacteria that are able to survive and grow within the body causes infection (e.g., *Listeria monocytogenes, Salmonella spp.*). Ingesting toxins produced by the bacteria in the food causes intoxication (e.g., *Clostridium botulinum* toxin).

b. Virus

Viral hazards can cause illness by infection (e.g., hepatitis A virus, Norwalk virus) and can be transmitted via food when ingested.

c. Parasites

Parasitic hazards infect humans when they are consumed along with the food (*e.g., Cryptosporidium parvum, Giardia lamblia*).

d. Moulds

Moulds can cause illness by intoxication. Ingesting toxins produced by certain moulds in the food causes intoxication (e.g., aflatoxin produced by *Aspergillus flavus* in peanuts).

ii. Chemical Hazards

There are four categories of chemical hazards:

a. Naturally occurring hazards

Naturally occurring chemical hazards are derived from plants, animals or micro-organisms and are found prior to, or during harvest or slaughter. For example, some plants (e.g., rhubarb leaf, poisonous mushrooms) contain naturally occurring toxins.

makingthegrade

Some common sources of food safety hazards you should consider include:

- Contaminated incoming materials and ingredients
- Cross–contamination or recontamination during processing, packaging, storing or shipping
- Improper food handling practices
- Unsanitary equipment
- Inadequate processing (e.g., insufficient cooking or cooling too slowly)
- Improper storage conditions (e.g., condensation, temperature too high or too low).

technical**terms**

Pathogen:
micro-organism that can cause illness or disease in humans.

b. Intentionally added hazards
Intentionally added chemical hazards are added to the food during growth or food processing. These chemicals (e.g., sodium nitrite) are considered safe at established levels but are dangerous above these levels.

c. Unintentionally added hazards
Unintentionally added chemical hazards contaminate the food accidentally. They might be present in a food prior to processing (e.g., pesticides) or might be added at the processing facility (e.g., cleaning chemicals).

d. *Food allergens*
Food allergens are substances in food (e.g., fish, peanuts) that cause some individuals to experience an immune system response (i.e., an allergic reaction).

iii. Physical Hazards
Physical hazards include substances not normally found in food that can cause physical injury to the person consuming the food. They include items such as wood slivers, glass fragments, metal shavings and bone pieces.

iv. Cross-Contamination
HACCP systems control not only existing food safety hazards, but also those that can be introduced during the manufacturing process through cross-contamination. Cross-contamination is the physical movement, or transfer, of harmful micro-organisms, allergens, chemical contaminants or any foreign substance from one person, object or food product to another. Within a food manufacturing environment, there is often a risk of cross-contamination. For example, if a food product that is contaminated with a pathogen is placed by an employee on a surface, then the employee and the surface are both likely to be contaminated and could spread the pathogen to another food item or employee.

2. WHY IMPLEMENT HACCP?

New food production and processing practices, emerging food-borne pathogens, and changing eating habits and demographics have contributed to a higher awareness of food-borne illness in recent years. Increasingly, prevention has become the focus. HACCP systems control food safety hazards through prevention, elimination and reduction.

To address food safety concerns, market forces are driving HACCP implementation throughout the food continuum, particularly the processing sector.

When a food illness outbreak occurs, many points in the food continuum suffer, including the retail sector. In response, many retailers and grocers have begun to insist that their suppliers have effective food safety systems, including HACCP, implemented in their facilities. This action drives the adoption of HACCP by many processors to retain their current market and customer base or, in fact, expand it.

A. Common Benefits of HACCP

Although the adoption of HACCP systems worldwide is due primarily to the added food safety protection provided to the consumer, a number of other benefits to the food industry, including your company, can be realized by implementing a successful HACCP system.

i. Increased Focus and Ownership of Food Safety
Food safety is the responsibility of everyone in the food supply chain. Through the process of developing and implementing a HACCP system, your company's employees will become more aware of food safety and their roles in maintaining and contributing to food safety. This increased awareness leads to increased ownership and pride in the production of a safe product.

ii. Increased Buyer and Consumer Confidence
There is an increasing trend for buyers to request HACCP from their suppliers. Food processors who have implemented a HACCP system provide buyers and consumers with a greater degree of confidence that the facility is producing a safe food product.

iii. Maintaining or Increasing Market Access

Market forces continue to drive food safety awareness and HACCP implementation throughout the food processing sector. As food safety systems, particularly HACCP, become more common, market access is limited for processors who do not implement them. In many cases buyer demands require HACCP implementation to maintain market share and/or gain access to previously inaccessible markets. HACCP implementation may also permit re-entry into a market that had been lost. Considering the economic implications, HACCP implementation may be a necessary cost of business.

iv. Business Liability Protection

Implementation of a HACCP system can provide your facility with some degree of increased business liability protection and may lead to reduced insurance premiums.

v. Reduced Operational Costs

The process of developing and implementing a HACCP system requires that the entire manufacturing process be reviewed and analyzed, and written procedures developed. This process often reveals areas where operational costs can be streamlined. For example, developing a sanitation program may identify that excessive chemical concentrations are being used. Reducing chemicals to the correct concentration may decrease sanitation costs.

vi. Efficient Oversight

Similarly, HACCP implementation can provide your company with ongoing efficient oversight. It can be cost effective to implement HACCP in spite of the associated costs. Activities that are performed on a regular basis, such as product and process monitoring, employee training and review of procedures, allow your company to maintain control over the facility and product. You may find there are certain areas of the process that can be made more efficient and productive.

vii. Improved Product Quality and Consistency

The implementation of a HACCP system may indirectly enhance product quality. Procedures that minimize the presence and growth of pathogenic micro-organisms can also minimize the presence and growth of spoilage micro-organisms, leading to an increased product shelf life. In addition, the attention given to standardized procedures will improve product consistency.

viii. Reduced Wastage

The preventative nature of HACCP allows a company to control costs by minimizing the amount of product requiring rework or rejection, and focusing resources on areas that have been identified as critical in the manufacture of a safe food product. You will find that many problems are addressed before they escalate and before products are shipped from your facility; you will not simply be waiting for the results of end-product testing. With the regular monitoring inherent in a HACCP system, you will become aware of problems earlier, and your costs of wastage will be reduced.

3. IS MY FACILITY READY FOR HACCP?

A. Considerations Before Implementing HACCP

Of course, improving food safety commonly involves some cost and does not guarantee future cost savings. For this reason, many companies are initially hesitant to implement HACCP since money and resources are usually limiting factors.

The development, implementation and maintenance of a HACCP system is a major commitment that will require time, money and other resources. It is highly recommended that you do some preliminary assessments to determine if HACCP is right for your company. The following considerations will help you with your assessment.

Ask yourself:
- Do you have a thorough understanding of your facility and its operations?
- Why do you want to implement HACCP?
- What resources would be required to implement HACCP in your facility?
- What are the costs and benefits of implementing HACCP in your facility?

Quiz: Do You Have a Thorough Understanding of Your Facility

Statement	**Yes or No?**
1. I can describe all the products manufactured in my facility.	
2. I can list the main ingredients, incoming materials (e.g., processing aids) and packaging materials of all of these products.	
3. I can describe the processes used for all of these products.	
4. I can describe the main food safety hazards (chemical, biological, physical, cross-contamination) of all of the products and processes in my facility.	
5. I can describe the purpose of each piece of equipment in my facility and how each is used.	
6. I understand the maintenance and calibration requirements of each piece of equipment in my facility.	
7. I am fully aware of the physical condition (e.g., state of repair) of my facility inside and out.	
8. I understand how each area of my facility is used.	
9. I can describe the flow of people and products through my facility.	
10. I understand the role each employee plays in the processing of products, and the handling of products, ingredients and packaging materials.	

How did you score?

If you answered "Yes" to all of the above, you have a thorough understanding of your facility that will assist you to develop a successful HACCP system.

If, however, you were not able to answer "Yes" at this point to all of the above, now is the time to gain a greater understanding, before you are too far into the development of your HACCP system.

Failing to gain a greater understanding of your facility will hinder and jeopardize your HACCP system. For example, you may misunderstand certain hazards, overlook key areas of cross-contamination or miss the impact of certain employees.

B. Why Do You Want to Implement HACCP?

You have read about the common benefits of HACCP listed above; now you can estimate the benefits your company could expect from HACCP implementation. Take some time to realistically set out your specific goals. Write these down, and go back to them from time to time. Perhaps HACCP certification is necessary to simply maintain your current markets and avoid sale losses. Or perhaps you have experienced losses that could have been mitigated by HACCP, such as too-frequent recalls.

Some components, such as increased buyer confidence, will be difficult to measure. You may need to estimate the value of these intangibles in more general terms. You may also want to speak with others who have implemented HACCP to gain a better understanding of potential benefits.

To help you define your goals, a sample is provided below.

Table 2.1: HACCP Expectations

Goal	**How HACCP would achieve goal**	**Benefit**
Increase sales	HACCP certification required by key buyer(s)	Increased profits
Reduce recalls	Detecting problems through monitoring before shipment	Reduced costs

C. What Resources Will Be Required to Implement HACCP in Your Facility?

To determine the resources needed in your facility, you need to be aware of some of the potential costs of HACCP.

i. Factors Affecting the Costs of HACCP

There are undoubtedly some costs associated with the implementation of HACCP; however, these costs vary significantly depending upon several factors. The first two to consider are the number of products and processes in your facility, and their associated risks. You should also consider the condition of your facility and equipment, and your employee food safety training.

a. Number of products and processes

In general, the greater the number of products and the more varied these products, the greater number of HACCP plans required. Furthermore, the more complex your process, the more work required for HACCP plan development and implementation. If your operation is simple (e.g., producing one product by few processing steps) you may need only one simple HACCP plan.

b. Associated risks (food safety hazards) of your products, ingredients and processes

When considering the associated food safety risks of your products you should think about:

- The intended use (e.g., ready-to-eat, further processed) and intended consumer
- The risks associated with ingredients including the use of restricted ingredients and the presence of allergens.

You should also consider any hazards introduced during processing. The more risks inherent to the product and introduced during processing, the more controls required in your HACCP system.

c. Condition of your facility

The existing condition of your facility can have a great impact on the costs of HACCP implementation. If, for example, the building structure is old, with surfaces that are not cleanable or that allow the entry of pests, you may require significant capital upgrades. If, however, your facility is currently in a better condition, you may require few structural or surface changes.

d. State of your equipment

The state of your current equipment is also relevant to the costs of HACCP. HACCP requires equipment that is accurate and that consistently achieves the intended purpose (e.g., oven temperature). Equipment, particularly pieces that come into contact with food, ingredients or packaging materials, must also be cleanable and in a good state of repair. Any deficiencies in the state of your equipment must be addressed through repair, adjustments or replacements. You may also need to purchase new equipment for certain monitoring processes (e.g., a thermometer that can be calibrated, pH meter, and metal detector).

e. Level of food safety understanding and training of your employees

All employees need to have a firm understanding of food safety and sufficient training to conduct their HACCP responsibilities. In estimating your costs for training, you should consider the:

- Number and positions of employees
- Current or recent food safety training
- Number of languages commonly understood
- Employee turnover rate.

ii. One-Time Costs and Recurring Costs

The costs for the development, implementation and maintenance of a successful HACCP system fall into two general categories: one time and recurring. One-time costs are usually those associated with the planning, development and implementation of the HACCP system. Recurring costs are those incurred from maintenance activities such as training, record keeping and monitoring, and updating. You cannot avoid or skimp on these recurring costs; for a successful HACCP system with continued recognition and certification, these activities must be done.

iii. Estimating Costs in your Facility

Once you have a basic understanding of HACCP and understand the potential costs, assess your operation to estimate the resources required. At this early stage you may not have enough information to completely and thoroughly estimate recurring costs, but do attempt to include some general estimates for ongoing training, record keeping and monitoring, and updating your system. As you determine the necessary resources for your situation, you may find it useful to develop a table like the sample (Table 2.2) provided on the next page.

The costs to consider include the following:

- Need for facility upgrades and construction
- Need for new or modified equipment
- Need for supportive materials (e.g., logbooks, software, measuring devices)
- New staff wages or consultant fees, if required
- Labour and time of existing staff for development, training, record keeping and monitoring, maintenance and updating.

Table 2.2 Estimating Costs for HACCP System Development, Implementation, and Maintenance

Resource item	**Input** (e.g., upgrades, purchases, fees, wages)	**Estimated costs**
Facility structures		
Equipment		
Food safety training		
Supporting materials		
Hiring new staff or consultants		
Monitoring activities (labour)		
Updating system		

D. What Are the Costs and Benefits of HACCP for Your Facility?

With realistic goals, expectations and estimates of resources and costs in hand, you can now conduct a basic cost-benefit analysis of HACCP for your facility. You will compare the estimates of costs with the estimates of benefits to determine if HACCP implementation will, in the end, be profitable for your company.

Table 2.3 Weighing the Costs and Benefits of HACCP

Benefits		**Costs (one time and recurring)**	
Tangible benefits	Approximate dollar value	Tangible Costs	Approximate dollar value
List benefits such as increased sales		List costs such as structural upgrades, ongoing monitoring	
	$		$
	$		$
	$		$
Total Benefits:	$	Total Costs:	$
Intangible Benefits	Value (in other terms e.g., rating how important)	Intangible Costs	Value (in other terms e.g., rating how important)
List benefits such as improved employee ownership		List costs such as less flexibility in adding product lines	

You could also hire an expert to assist you in the cost-benefit analysis. Some consulting companies conduct formal cost–benefit analyses for companies considering HACCP implementation.

4. FACT AND FICTION

A. Quiz: Test Your HACCP Knowledge

Statement	T or F
1. HACCP is a quality control system.	
2. HACCP is a government-implemented program.	
3. HACCP is maintenance free after implementation; you just need to do the initial paperwork and implement the system, and you can become certified.	
4. HACCP controls all hazards and is the solution to every problem.	
5. HACCP is zero risk.	
6. HACCP is for food manufacturing facilities only.	
7. HACCP presents the same obstacles for all companies.	
8. HACCP controls only bacterial hazards.	
9. HACCP applies only to certain commodities.	

How did you score?

If you answered "true" to any of the questions, keep reading to learn more HACCP facts.

If you answered "false" to all of the above, you've gained a realistic understanding of HACCP, but you may still want to read the following section on HACCP facts.

B. HACCP Facts

It is important to remember that HACCP…

i. Is *Not* a Food Quality Control System

HACCP systems are designed to enhance food safety. However, implementing a HACCP system may lead to increased food quality attributes.

ii. Is *Not* a Government-Implemented Program

A HACCP system must be implemented and maintained by the operator, who is responsible for the effectiveness of the system. Success is unlikely if the operator does not take full ownership of the system. Therefore, HACCP places more responsibility for ensuring food safety on the food manufacturer than do traditional inspection programs. The people manufacturing the product have the most control over the product, and thus their actions can have a great impact on the safety of the product produced.

iii. Is *Not* Maintenance Free

Once a HACCP system has been developed and implemented, ongoing activities are required to maintain it. The written policies and procedures that have been developed cannot simply be left on an office shelf. Control measures within the facility must be monitored on a regular basis, new employees must be trained and many other tasks must be performed continually. In addition, any new products or processes must be included in the HACCP system.

iv. Is *Not* the Solution to Every Problem

It is important to remember that a HACCP system may not be able to control all potential hazards. For example, an operator may have little control over some of the raw materials received and likely will not have control of the product once it reaches the retail establishment.

v. Is *Not* Zero Risk

HACCP is not a zero-risk system, but rather a system designed to enhance the safety of the food produced. A HACCP system is designed to prevent, reduce or minimize potential food safety hazards. Ideally, all hazards would be prevented; however, there are instances when this may not be possible. For example, raw ground beef, unless irradiated, may contain pathogens. It is also possible that even if a HACCP system is implemented, a food safety hazard may occur. Nevertheless, a well-designed HACCP system would detect this hazard and prevent the distribution of the product or allow for an effective recall.

vi. Can Be Implemented throughout the Food Continuum

HACCP principles can be applied to all segments of the food chain, from the primary producer to the final consumer. A HACCP system can be implemented in any facility, regardless of size or volume of product processed.

vii. Presents Different Obstacles

The principles of HACCP are the same whether a facility is very small or very large; however the challenges are different. For example, smaller facilities might face financial or human resource constraints. Smaller facilities are also more likely to be lacking in technical support, may have inadequate infrastructure and facilities, and may also have less customer demand for HACCP.

viii. Controls Biological, Chemical and Physical Hazards

As mentioned earlier, the purpose of HACCP is to control all significant food safety hazards.

ix. Applies to All Food Commodities

HACCP systems can be implemented for all food commodities. Whether you are processing vegetables or baking bread, HACCP principles can be applied. The *HACCP Advantage* standards are universal and apply to all food commodity sectors.

IN SUMMARY

After reading this chapter, you should be able to provide answers to the following questions:

1. What is HACCP, and what can and can't it do for your company?
2. Why do you want to implement HACCP?
3. What resources will be required to implement HACCP in your facility?
4. What are the costs and benefits of implementing HACCP in your facility?

Points to remember

- HACCP is a preventative and science-based food safety system. HACCP systems consist of prerequisite programs and HACCP plans.
- Successful HACCP implementation requires an understanding of the costs and benefits. Before you develop your HACCP system you should determine resources required and assess your individual business situation.
- Before you can implement HACCP in your facility you need to be thoroughly aware of the activities within and the condition of your facility. Without this understanding you will not be able to successfully develop your HACCP system.

CHAPTER THREE

Overview of the Main Phases

Key Points in Chapter 3

Developing and implementing a HACCP system requires planning.

Management commitment is essential for a successful HACCP system.

You must have designated personnel responsible for the HACCP system.

You may need to obtain HACCP training and/or resources.

Once implemented, HACCP systems must be maintained over time.

Overview of the Main Phases

HOW TO BEGIN DEVELOPING A HACCP SYSTEM

The development, implementation and maintenance of a HACCP system requires planning and commitment. Implementing a HACCP system is not something that can be accomplished overnight. Most HACCP systems take months or even a year or more to implement. Be prepared for a long-term project; trying to implement a HACCP system with a very short deadline can lead to corner cutting, and frequently the ultimate audit result is failure. Planning ahead and preparing to implement HACCP over a long period of time with clear milestones will vastly reduce this risk.

Once you decide that you are ready to implement HACCP, you should:

1. Obtain management commitment
2. Form a HACCP team, and assign a HACCP coordinator
3. Acquire necessary training
4. Develop an implementation schedule
5. Obtain the necessary resources
6. Develop and implement prerequisite programs
7. Develop and implement HACCP plan(s)
8. Perform HACCP system maintenance, including verification and validation
9. Apply for certification

These are the main steps that you should go through, regardless of facility size, processing complexity, or food produced, when implementing a HACCP system. Remember that this is just a summary—these steps will be explained in more detail in subsequent sections of this guidebook.

1. OBTAIN MANAGEMENT COMMITMENT

Many HACCP experts have stated that the single most frequent reason a HACCP system fails is lack of management commitment.

A. What Is "Management Commitment"?

Management commitment is the endorsement and involvement of the facility's top management (generally, this means the owner or president/CEO) in the decision to not only proceed with HACCP but also stick with it when times may become trying. When implementing a HACCP system, decisions regarding a facility's financial, time, and labour resources will need to be made. Many major financial decisions commonly involve the choice between spending now or spending later. Low, short-term costs may result in higher, long-term costs. Conversely, high short-term costs can result in low long-term costs. For example, permanently improving the floor drainage in a problem area can be very costly to fix. Alternatively, staff could spend time ensuring that no water accumulates in the problem area by consistently monitoring and removing any pooled water. Over time these labour costs, as well as the increased risk of cross-contamination, will outweigh the costs of fixing the floor permanently. So when do you plan to permanently fix the floor? Decisions of this nature will need to be made by individuals who are committed to the program and have the authority to make such decisions.

It is not necessary for senior management to be part of the HACCP team—although this is always a good idea but they should always be accessible to make decisions in a timely manner. Senior management must be dedicated to HACCP implementation from the onset. If there is a lack of commitment, including lack of financial or labour resources, the HACCP system may not be properly implemented. This may lead to an increased chance of system failure. Upper management must be fully aware of HACCP and the benefits to be realized through a HACCP system. They also need to understand the challenges the facility may face.

didyou**know**

HACCP has many benefits including:

1. Increased food safety
2. Increased focus and ownership of food safety
3. Increased buyer and consumer confidence
4. Increased market access
5. Business liability protection
6. Reduced operational costs
7. Efficient oversight
8. Improved quality and consistency
9. Reduced wastage

B. How Can You Gain Management Commitment?

Management commitment can be gained by promoting the benefits of HACCP to management. Point out that HACCP will likely become a cost of doing business in the food processing industry.

- Talk to your customers, and inform management of their view. Most companies are very supportive of their suppliers implementing HACCP and, in some instances, will provide some assurance about the future of the business relationship (such as new contracts, premium prices).
- Try to find out if your competitors have HACCP. If they do, they may have a competitive advantage, possibly jeopardizing your future business. If not, you could have the competitive advantage through implementation of a HACCP system.

C. How Is Management Commitment Demonstrated?

Management can establish that they are committed to implementing HACCP in a number of ways. From management's point of view these include:

- Openly stating to facility employees during meetings and through other avenues (e.g., signage) that HACCP is important and will be implemented
- Initiating and attending HACCP team meetings or HACCP-related training sessions
- Making sure that they themselves are aware of and adhere to all applicable HACCP-related procedures and policies whenever they are in the facility
- Purposefully determining and allocating resources to the HACCP coordinator for the development and implementation of HACCP
- Requesting and reviewing periodic progress reports on the status of the HACCP system
- Implementing disciplinary consequences for facility employees who fail to fulfill their HACCP responsibilities
- Attending HACCP audit opening and closing meetings and introducing themselves to the auditors
- Visibly supporting the HACCP team when difficult decisions need to be made.

All of these items will clearly send a message to the HACCP team, facility employees and all external parties that review the HACCP system that management is involved and cares about the program.

2. FORM A HACCP TEAM, AND ASSIGN A HACCP COORDINATOR

The HACCP team is the group of people involved in the development, implementation and maintenance of the HACCP system. There is no requirement for the number of people on the HACCP team, and the number will vary based on the complexity of the process and the number of employees. At minimum, the HACCP team can be made up of one person who oversees the development of the entire HACCP system. Obviously, the person in this role will need to have a very good understanding of the facility and its products, as well as HACCP. This type of situation usually occurs in very small plants with a limited number of staff and/or resources and very rarely occurs in large plants.

Forming the HACCP team with the right personnel for the job is a key step toward implementing an effective HACCP system. Preferably, the HACCP team should comprise individuals with expertise from different areas of the plant, such as:

- Quality assurance
- Production
- Maintenance
- Sanitation
- Shipping and receiving
- Management

The HACCP system encompasses all areas and aspects of the facility. Including people with expertise and knowledge of all current plant operations and conditions is important because they will:

- Assist with developing HACCP policies and procedures for their area of expertise
- Be aware of existing policies and procedures that do not need to be reinvented to meet HACCP requirements
- Likely play a role in carrying out HACCP activities in their area.

One person on the HACCP team should serve as the HACCP coordinator. This person is responsible for overseeing the overall development and implementation of the system. The HACCP coordinator should have a solid understanding of HACCP and how it works, and a working knowledge of the facility and the products manufactured. One of the main roles of the HACCP coordinator will be to monitor the team's progress with respect to HACCP implementation.

If no company employees are knowledgeable about HACCP, there are a couple of possibilities:

1. The HACCP coordinator can source and complete pertinent HACCP training (see the next section).

2. Hire a HACCP consultant to fill the role of HACCP coordinato

Consultants are independent firms that can provide knowledge and support during HACCP implementation. If you do your homework and hire the right consultant, you can access a valuable and effective HACCP knowledge resource. When hiring a HACCP consultant, remember to:

- Ask for, and check, references
- Ask for, and look at, samples of other HACCP work the consultant has done
- Ask for a written quote for any proposed work
- Ask how closely the consultant will be working with plant employees and how often the consultant will be in the facility
- Ensure the consultant understands what material you wish to remain confidential and have him or her sign a confidentiality agreement
- Ensure that you have a contract for any services the consultant is hired for
- Ensure that you understand the consultant's responsibilities, if any, following implementation.

Currently the HACCP consultant field is not regulated, meaning "buyer beware." Ensure that you understand the services you may be purchasing. Bear in mind that hiring a HACCP consultant is an acceptable avenue to take, but the consultant will not have a working knowledge of your facility and will therefore need to work closely with a facility representative to ensure success.

3. ACQUIRE NECESSARY TRAINING

All personnel need to understand their role in ensuring food safety and follow applicable company policies and procedures.

It may be apparent that the individuals on your HACCP team, while very skilled with respect to their current duties, do not have a working knowledge of HACCP. Different personnel will require varying levels of HACCP knowledge.

HACCP coordinators should be knowledgeable of:

- Food safety hazards common to their products and processes
- Good Manufacturing Practices applicable to their facility
- Applicable regulatory requirements
- Importance of management commitment
- Use of HACCP for the manufacture of safe food
- Purpose of prerequisite programs
- Purpose of HACCP plans
- HACCP principles, including hazard analysis and determining critical limits
- Concepts of monitoring, corrective actions and verification
- Importance of record keeping
- Specific requirements of the *HACCP Advantage*
- Audit principles and internal audits
- Process for certification and recognition.

At minimum, management should be knowledgeable of:

- The importance of their role with respect to HACCP
- Benefits and costs of HACCP
- Resources required for HACCP implementation and certification.

Other personnel, should, at minimum, be knowledgeable of their roles and responsibilities within the HACCP system including:

- Importance of appropriate control measures
- How to perform specific tasks (e.g., monitoring, taking corrective actions, record keeping).

This knowledge may be acquired in many different ways, such as:

- Taking food safety and HACCP-related courses
- Reading the *HACCP Advantage Program Manual* and *Guidebook*
- Applying food-processing environment experience
- Being aware of regulatory requirements
- Researching necessary topics (e.g., reading scientific literature)
- Communicating with appropriate experts (e.g., sanitation company, government authority)
- Hiring HACCP trainers or consultants.

Many HACCP trainers would be willing to perform HACCP training at your facility. If you choose this route, you may want to ask the trainer to include examples specific to your facility in the training material. It is also possible for the HACCP coordinator to provide training to the rest of the facility employees once the coordinator is adequately knowledgeable and comfortable in delivering HACCP training.

4. DEVELOP AN IMPLEMENTATION SCHEDULE

The HACCP coordinator should use his or her knowledge of HACCP to determine the major tasks required to implement HACCP in the facility. Next, the HACCP coordinator should present to the HACCP team a rough explanation and outline of the tasks to be completed. The number and rigor of these tasks may vary depending on existing food safety programs within the facility.

With this rough idea of the major tasks, the HACCP team should develop an implementation schedule and itemize each of the tasks. An implementation schedule is simply a chronological schedule or list of events that need to take place in order for a HACCP system to be developed and implemented successfully. Each event or task on the schedule should include an estimated start date and completion date. Be sure to err on the side of caution and allow more rather than less time—no one can predict the roadblocks you may encounter.

Once the major tasks have been itemized on a schedule they should then be assigned to the individuals best suited to complete them (usually the other HACCP team members). If delays completing certain tasks occur, the HACCP coordinator should review the implementation schedule and make appropriate changes to other tasks that are also affected by the delay.

In many cases, especially with small HACCP teams, many or all of the major tasks may be assigned to the HACCP coordinator. This is fine; just be sure that the time allotted to complete the tasks is feasible for one person.

5. OBTAIN THE NECESSARY RESOURCES

Once the schedule and task lists have been created and assigned, a rough list of the resources that are, or may be, required can be formed. This may include:

- Further knowledge resources such as consultants, engineers or specific area experts
- Sanitation or pest control services
- New equipment
- Monitoring devices (e.g., thermometers)
- New construction materials or services
- Plant or personnel supplies (e.g., hairnets, waste containers)
- Treatment chemicals (e.g., for water treatment)
- Laboratory services and/or supplies

Keeping an eye on the cost of implementation as each item is checked on the list will help the budgeting process. Tracking these costs, keeping a budget and providing frequent reports to management may be useful.

It may be impossible to determine or foresee all of the resources that may be required for HACCP implementation. However, having a preliminary list that itemizes resources required will prepare management in advance, allowing them to make financial decisions.

6. DEVELOP AND IMPLEMENT PREREQUISITE PROGRAMS

Prerequisite programs are developed and implemented using the *HACCP Advantage* standards (as defined in the *HACCP Advantage Program Manual*).

To learn how to develop and implement prerequisite programs, refer to Chapter 6 of this guidebook.

7. DEVELOP AND IMPLEMENT HACCP PLAN(S)

HACCP plan(s) are developed and implemented using the *HACCP Advantage* forms (as provided in the *HACCP Advantage Program Manual*).

To learn how to develop and implement HACCP plan(s), refer to Chapter 7 of this guidebook.

8. PERFORM HACCP SYSTEM MAINTENANCE, INCLUDING VERIFICATION AND VALIDATION

After developing and implementing a HACCP system, it must be maintained on an ongoing basis. This includes ensuring that the system is effective and functioning as intended (these are the concepts of validation and verification). It is important that you record any changes or additions.

For information on maintaining a HACCP system, refer to Chapter 8.

9. APPLY FOR CERTIFICATION

Once the HACCP coordinator is confident that the HACCP system is complete and effective, your organization can apply for certification. The certification process for the *HACCP Advantage* is administered through the Canadian General Standards Board (CGSB). For information on the certification process, refer to Chapter 9 of this guidebook.

The certification process involves objective and independent auditors visiting your facility to assess your HACCP system. If the system meets the *HACCP Advantage* requirements and is being followed as written, your system will be certified.

IN SUMMARY

After reading this chapter, you should be able to provide answers to the following questions:

1. What are the nine steps of HACCP system development and implementation?
2. What is management commitment, and how can I gain it?
3. Who should be included on my HACCP team?
4. What are the benefits of a HACCP implementation schedule?
5. Why is the job of the HACCP coordinator not finished with implementation? Why not?

When you have no problem answering these questions, you are ready to proceed on to the next couple of chapters to learn more about the specific components of the *HACCP Advantage*. These components include record-keeping you will need to keep in mind before you proceed on to the process of designing your own system.

Points to remember

- Implementing a HACCP system is a long-term commitment that will require continual effort and attention.
- Developing a plan for implementing a HACCP system will make the process easier.
- Forming a good HACCP team and having management commitment is essential.

CHAPTER**FOUR**

An Introduction to the *HACCP Advantage*

Key Points in Chapter 4

The *HACCP Advantage* consists of 57 prerequisite program standards, and 8 HACCP plan forms.

You must meet all applicable food safety legislation and regulations.

A *Food Safety Management System* (FSMS) is required for *HACCP Advantage* certification.

CHAPTER **FOUR**

An Introduction to the *HACCP Advantage*

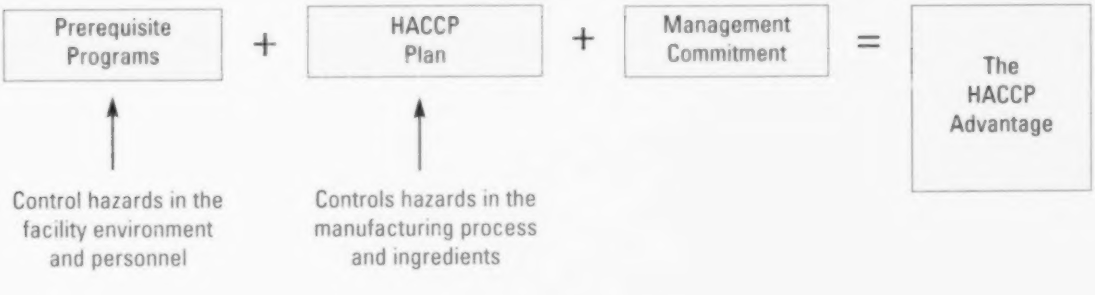
The *HACCP Advantage* program has been developed by the Ontario Ministry of Agriculture and Food. The program has been designed to be practical and feasible for all facilities, regardless of size or commodity processed. The *HACCP Advantage* consists of 57 prerequisite program standards and 8 HACCP plan forms.

Some consumers may wonder "Don't we already have systems in place to ensure the safety of the food we eat?" The simple answer is "Yes, we do." Governments have a clear and important role in maximizing food safety for Canadians and people around the world who eat Canadian exported products. To that end, legislation such as the Ontario *Health Protection and Promotion Act*, and the Canada *Food and Drugs Act* have been developed.

Programs such as the *HACCP Advantage* complement regulations and provide a tool to apply consistency and universality to food processing plants. Additionally, HACCP programs empower the industry to accept its share of food safety responsibility. Producers, processors, distributors and retailers of food products all directly manufacture and handle the food products we all eat. These groups have the most direct influence to ensure that these products are indeed safe. With a program like HACCP, industry can lead the way to improved food safety through the entire food continuum. HACCP promotes a shared system of responsibility with all involved stakeholders—government, producers, processors, retailers and consumers.

1. THE *HACCP ADVANTAGE* COMPONENTS

Figure 4.1: HACCP Advantage Equation


Prerequisite Programs
+
HACCP Plan
+
Management Commitment
=
The HACCP Advantage
Control hazards in the facility environment and personnel
Controls hazards in the manufacturing process and ingredients

Apart from the important component of management commitment, the *HACCP Advantage* is divided into two sections, prerequisite programs and HACCP plans.

The prerequisite programs include 57 standards that are designed to create a safe and suitable food processing environment. These standards are designed to control hazards that are associated with the overall facility structure and condition, equipment and tools that are used, and all personnel who come into contact with food and ingredients within the facility.

The eight HACCP plan forms focus on controlling food safety hazards associated with the food product or ingredient, or the specific food manufacturing process. Some common hazards associated with food products or ingredients include bacteria, allergens, pesticides, and antibiotics. Hazards that might be associated with a specific manufacturing process include metal filings from machine processing, illegible or incorrect labelling, and glass contamination.

To illustrate the difference between prerequisite programs and HACCP plans let's consider an example. Condensation is a hazard that can cause bacterial contamination; if condensation drips directly onto a ready-to-eat meat processing line, it could present a source of contamination and result in food-borne illness. The hazard of dripping condensation is associated with the facility (i.e., the ceiling or overheads are improperly maintained or the room has ineffective ventilation), not the food product or manufacturing process. This hazard is controlled by the *HACCP Advantage* prerequisite program, E3.4 Air Quality and Ventilation.

In contrast, pathogenic bacteria present in the raw ingredients of a ready-to-eat meat product would be controlled during the cooking processing step. Therefore, since this hazard is associated with the product and not the environment, it would be controlled by the HACCP plan and the cooking process would become a Critical Control Point (CCP).

2. FOOD SAFETY MANAGEMENT SYSTEM (FSMS) REQUIREMENTS

In addition to meeting *HACCP Advantage* program requirements for your facility to be certified, you must also implement a Food Safety Management System (FSMS). Chances are that this will be relatively simple as you should already be meeting most of the requirements of an FSMS.

An FSMS refers to a system that ensures that your facility complies with all mandatory food safety-related programs and requirements or those that management has chosen to do of their own accord. The *HACCP Advantage* program is part of the FSMS, as management has chosen to develop and follow it. If a facility has only developed and implemented a sanitation program or a Good Manufacturing Practices (GMP) program, these programs could also be considered part of an FSMS, even though they haven't met the full requirements of a HACCP program. However, there are food safety-related programs that some facilities may be *required* to meet. By this, we mean any legislated food safety regulations or standards that are mandated by the government. Some of these requirements are broad and apply to all processors. Others are more focused and apply only to very specific commodity sectors within the food processing industry.

For example, the provincially licensed abattoirs in Ontario are required to meet the *Meat Inspection Act* (Ontario) O.Reg.632/92. Regulations are enforced, so all provincial abattoirs should be aware of and complying with the regulation. The same can be said for dairy facilities and the *Milk Act* (Ontario) O.Reg 761. Both of these pieces of legislation are mandated and administered by OMAF, the same ministry that has developed and published the *HACCP Advantage.*

In addition, all food processors, regardless of commodity, are required to meet the *Health Protection and Promotion Act* (Ontario) O.Reg. 562; *Food and Drugs Act* (Canada); and the *Consumer Packaging and Labelling Act and Regulations.* This legislation applies to all food handlers including processors, distributors, food service establishments, restaurants and retailers.

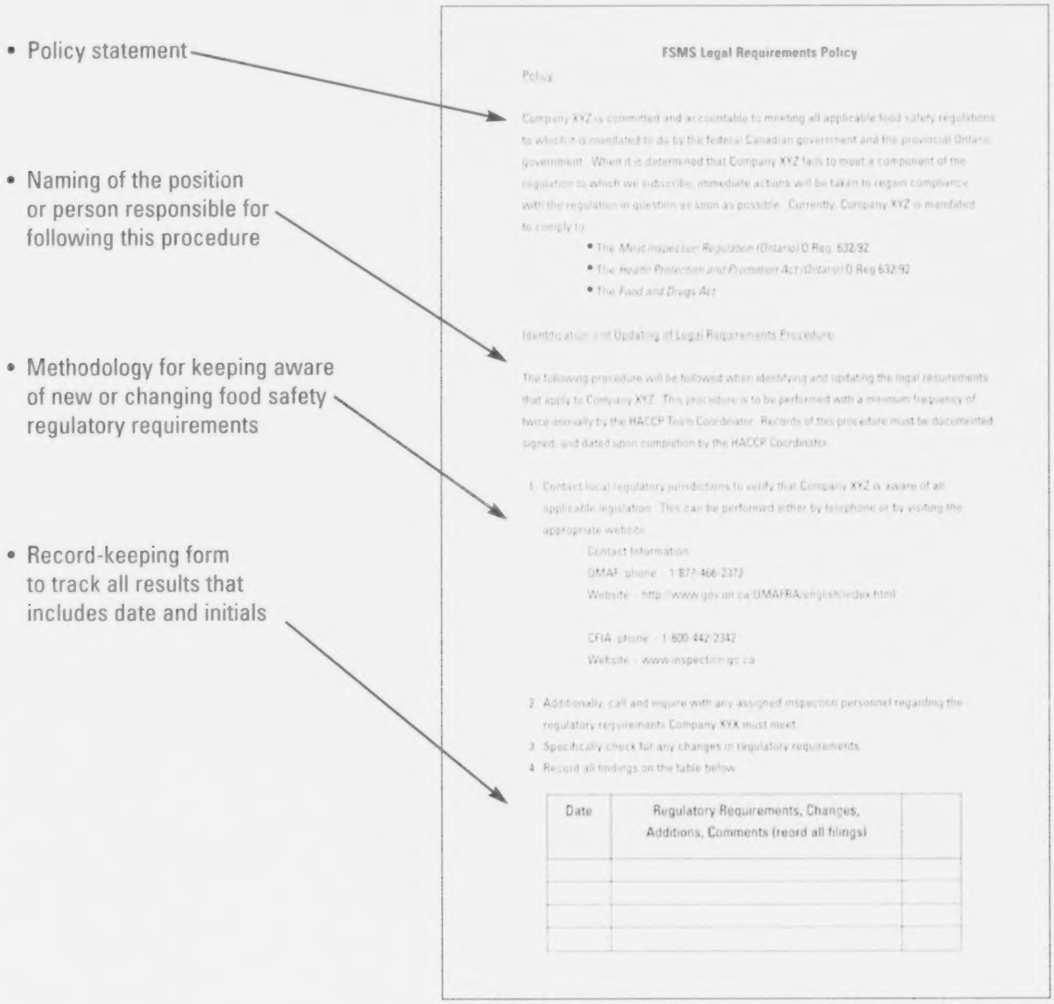
The FSMS requirement doesn't mean that during the *HACCP Advantage* certification process auditors will audit all of the applicable pieces of legislation to which the applicant must abide. These pieces of legislation already have an inspection and enforcement framework to ensure compliance. However, the auditors will check some things to ensure that applicants are meeting FSMS requirements.

The auditors will verify that you have the following:

- A policy statement that commits to observing and following all applicable legal requirements
- A documented method for identifying all applicable laws
- A documented method for keeping current with changes in legal requirements (i.e., a monitoring mechanism for identification of all applicable laws)
- A named and documented (i.e., written in policy) person designated by senior management as responsible for the FSMS.

By completing all of the items above you can demonstrate that you are aware of and meeting any applicable regulatory requirements. Here are some examples of how you could meet all of the above requirements with one policy document:

Figure 4.2: Example FSMS Policy


• Policy statement
• Naming of the position or person responsible for following this procedure
• Methodology for keeping aware of new or changing food safety regulatory requirements
• Record-keeping form to track all results that includes date and initials

FSMS Legal Requirements Policy

Policy

Company XYZ is committed and accountable to meeting all applicable food safety regulations to which it is mandated to do by the federal Canadian government and the provincial Ontario government. When it is determined that Company XYZ fails to meet a component of the regulation to which we subscribe, immediate actions will be taken to regain compliance with the regulation in question as soon as possible. Currently, Company XYZ is mandated to comply to:

- The *Meat Inspection Regulation (Ontario)* O Reg. 632/92
- The *Health Protection and Promotion Act (Ontario)* O Reg 632/92
- The *Food and Drugs Act*

Identification and Updating of Legal Requirements Procedure

The following procedure will be followed when identifying and updating the legal requirements that apply to Company XYZ. This procedure is to be performed with a minimum frequency of twice annually by the HACCP Team Coordinator. Records of this procedure must be documented, signed, and dated upon completion by the HACCP Coordinator.

1. Contact local regulatory jurisdictions to verify that Company XYZ is aware of all applicable legislation. This can be performed either by telephone or by visiting the appropriate website.
   Contact Information:
   OMAF: phone – 1-877-466-2372
   Website – http://www.gov.on.ca/OMAFRA/english/index.html

   CFIA: phone – 1-800-442-2342
   Website – www.inspection.gc.ca
2. Additionally, call and inquire with any assigned inspection personnel regarding the regulatory requirements Company XYX must meet.
3. Specifically check for any changes in regulatory requirements.
4. Record all findings on the table below.

Date	Regulatory Requirements, Changes, Additions, Comments (reord all filings)	

Meeting the requirements that the auditors will be checking with respect to your FSMS obligations should not be difficult, especially if you are already in compliance with all applicable regulations. More often then not, this document will be one of the first things the auditors will review when beginning a certification audit.

IN SUMMARY

After reading this chapter, you should be able to provide answers to the following questions:

1. What are the main components of the *HACCP Advantage* program?
2. What types of hazards is the prerequisite program portion of the *HACCP Advantage* meant to control?
3. What types of hazards is the HACCP plan portion of the *HACCP Advantage* meant to control?
4. What is an FSMS?
5. Why is an FSMS important and what types of things should be included in an FSMS policy?

No problem with those questions? Great! Let's move on to the next chapter and to better understand what record control and retention is and why it's so important.

Points to remember

- The *HACCP Advantage* is composed of a prerequisite program section and HACCP plan section; management commitment is also essential.
- Prerequisite programs control hazards associated with the facility environment and the facility personnel.
- HACCP plans control hazards associated with the specific food, ingredients or food manufacturing process.
- An FSMS ensures that you are meeting all legislated food safety regulations and is required in order to be certified under the *HACCP Advantage*.

CHAPTER FIVE

Documenting Your HACCP System

Key Points in Chapter 5

Proper documentation of your HACCP system is integral to its success.

Prerequisite programs, HACCP plans, corrective actions and all other HACCP-related information need to be documented or recorded properly.

Methods to combine, streamline and organize records make the record-keeping process easier.

Documenting Your HACCP System

QUIZ: TESTING YOUR UNDERSTANDING OF DOCUMENTATION

Try this quiz now and then again after you have finished reading this chapter.

Are the following statements true or false in terms of HACCP activities?	**True**	**False**
1. Documents are the same as records.		
2. Anyone at the facility can record data or monitoring results.		
3. Your prerequisite programs are considered to be documents and records.		
4. Records can be completed at any time of the day or during your shift.		
5. It is better not to record data when something goes wrong.		

Answers

1. *False* Documents are written procedures or policies, whereas records are the data or results of HACCP activities.
2. *False* Only trained persons responsible for the activity can record data and results.
3. *True* The written programs are considered documents. The proof that the monitoring and corrective actions have been performed are records.
4. *False* Always record data as it is monitored. Information can be forgotten or misconstrued.
5. *False* Record everything. Remember that nothing in life is perfect. Without accurate record keeping showing deviations, it will be difficult to see a trend and fix problems.

1. WHY DOCUMENT THE SYSTEM?

A. Importance of Records

Record keeping is critical to maintain an effective HACCP system.
Well-maintained prerequisite program and HACCP plan records provide:

- Evidence that the system is properly designed and complete
- Evidence that the system has been implemented effectively
- Evidence that the company is conforming to the implemented system
- Evidence that employees have been trained
- The potential to identify trends and opportunities for improvement.

B. Documents and Records Explained

There is a key difference between documents and records. Documents are the written policies, procedures and record keeping forms that are developed when writing the prerequisite programs and the HACCP plans. Records are the result of recording the findings of monitoring, verification and corrective action activities on the record-keeping forms. The data recorded on these forms cannot be changed. That being said, the document form that the data is recorded on can be changed. *Documents can be changed; records cannot be changed.*

Documents are necessary for ensuring consistent implementation of your HACCP system (e.g., monitoring done in the same manner each time, by each person responsible). The person who develops your HACCP system must document the prerequisite programs and HACCP plans for future HACCP coordinators and consultants.

HACCP record keeping may seem like a lot of paperwork. However, some of your records may be kept on the same form. This guidebook and the Program Manual, provide you with many sample forms. You may want to use these forms "as is"; however, it is best to develop your own forms or tailor the sample forms to suit your unique needs.

Examples of HACCP Documents

- Food Safety Management System policy
- Written documents detailing how you meet the prerequisite program standards where necessary (e.g., sanitation program, recall program)
- Written HACCP plan forms and supporting documentation
- Written training materials and schedules
- Written documents detailing monitoring procedures for prerequisite programs

technical**terms**

Documents can be changed but must be controlled to ensure that the most current version is in use and old versions are removed from circulation. They outline policies, procedures, and other program requirements.

Records cannot be changed. They are static results or data that provide evidence that a specific action or procedure has been peformed.

Examples of HACCP Records

- Records on which prerequisite program monitoring results are recorded
- Records on which results from monitoring and verifying the CCPs are recorded
- Records indicating the names of employees who have received HACCP training
- Records demonstrating effective corrective action
- A logbook of changes to the HACCP system

Be proud of your accomplishments. Document all of your hard work.

2. HOW TO DOCUMENT THE HACCP SYSTEM AND RECORD RESULTS

When you begin writing your prerequisite programs and HACCP plans, you may find that you are already meeting many of the requirements of the *HACCP Advantage*. You may have to make only minor changes or additions to meet some of the requirements, or may have to simply improve the documentation surrounding your current programs. Therefore, as you develop your HACCP system, consider the programs, controls and records already in place. Whenever possible, use existing documents and record-keeping forms, or modify rather than re-create them.

A. Documenting Your Prerequisite Programs

For each prerequisite program standard, you must demonstrate how you are meeting the standard and document how you are monitoring the standard. For example, you should document:

- Written policies and procedures to meet the standard where necessary (e.g., GMP Policy, see Chapter 6)
- Monitoring procedures (who, what, when, how, records, corrective actions)

For each standard you must also create the records on which to record the results of monitoring and correction action activities. Refer to Chapter 6 for examples of prerequisite program documents and records.

B. Documenting Your HACCP Plans

You must develop a HACCP plan for each group of similar products your facility processes (Refer to "How Many HACCP Plans Will Your Facility Need" in Chapter 7). For each HACCP plan, you must complete the eight *HACCP Advantage* forms provided in the Program Manual or provide all of the information requested on these forms.

For each HACCP plan you must also create the records on which to record the results of monitoring, verification and correction action activities.

At minimum, documents that should be part of each HACCP plan include:

- A list of the HACCP team members and HACCP coordinator
- Completed forms 1–8, or equivalent
- The records used for documentation of monitoring procedures, corrective actions and verification procedures for each CCP
- The training instructions provided to each employee responsible for any part of a CCP.

Refer to Chapter 7 for examples of completed HACCP plan forms.

didyouknow

If you have enough space on your CCP monitoring record you can record your corrective actions on the same record. This can be a real time-saver whenever the HACCP coordinator is reconciling implemented corrective actions against recorded monitoring procedure deviations. For any forms that do not have an area to record corrective actions you may wish to create a separate Corrective Action Form. This form could then be attached to the CCP monitoring form.

C. Records and Record Keeping

Only trained, designated employees can record prerequisite program monitoring results and corrective actions. Similarly, only trained, designated employees can record CCP monitoring results, verification results and corrective actions. Certain employees may be trained and designated to perform multiple tasks and recording activities.

You may find it easier to combine record forms for multiple prerequisite program standards onto a single form, thereby consolidating and reducing the number of records you have to control. For example, when monitoring your operational GMP standards (O.1–O.9), you do not need a separate form for each. (Refer to the example at the end of this chapter).

To simplify your record keeping, you could record the monitoring results all on one record. During the audit, the auditors would then need to look at only one record for all of your GMP monitoring results, rather than nine different ones.

The following are example types of data that will be recorded when monitoring and verifying your HACCP system:

- Actual date and time that the monitoring and verifying are taking place
- Temperatures, pH levels or other quantifiable values relating to your prerequisite programs and HACCP plans
- Calibration of process-monitoring instruments
- Corrective actions, including all actions taken in response to deviations
- Initials of employee recording the data.

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- Never record data in pencil.
- Never pre-record data or photocopy it.
- Never postpone making a data entry.
- Never fabricate data entries or rely on your memory.
- Never "whiteout" or erase; strike out, correct and initial the change.

D. Recording Corrective Actions

Corrective actions must be recorded any time there is a deviation within your HACCP system. When a deviation occurs it is important to document the following:

- The date and time the deviation occurred
- What the deviation is
- What corrective actions are being taken (see "Corrective Actions" in Chapter 6 and "Form #8 HACCP Matrix" in Chapter 7 for information on corrective actions).
- The timeframe for completion of the corrective actions
- Sign-off by the responsible employee once the corrective actions are complete.

The form you use to record your deviations and corrective actions is up to you. For example, if there is enough space, you can record all of the information listed above directly on your monitoring record, preferably in a designated location. However, your monitoring records may not have enough room to record all of the information needed, so you may want to create a generic form that can be used for any deviation, and then attached to, or stored with, the monitoring record. The sample form below provides you with an idea of what a corrective action document might look like.

Figure 5.1 Example Corrective Action Request Record

CORRECTIVE ACTION REQUEST

Date: ____________________

Requested by: ____________________

Prerequisite Program or HACCP Plan: ____________________

Nature of Deviation:

____

____

____

____

Corrective Action Taken:

____

____

____

____

Verification that corrective action is effective: ____________________

Date: ____________________

E. Relationship to Audits

Record keeping provides evidence for certifying authorities or buyers auditing your HACCP system. To determine effective implementation of the HACCP system, the auditors will rely on your documents and records.

Consider the following scenario:

A buyer calls your facility and wishes to send auditors to your facility to perform an audit. The auditors come to your facility and want to see all the HACCP paperwork. You can provide them with the assurance that your products are safe because you will have well documented policies and procedures to show the auditors, and you will have records showing that these policies and procedures have been implemented effectively.

3. EFFECTIVE DOCUMENTATION TIPS

A. Clarity

You should aim for documents and records that are clearly understood by those who will read and use them. Some techniques to consider:

i. Identify Each Page
Put the name or title of the document on each page because it is easy for pages to become separated. Include the name of the prerequisite program or HACCP plan to which it applies.

ii. Number Pages
Number each page including the total number of pages in the document (e.g., 1 of 4).

iii. Highlight Revisions
When documents or record forms are changed or updated, use a method to point out the revisions. For example, use a different colour of paper and include a brief note listing the changes, or include the revision date in the header or footer.

iv. Explain Revisions
Give the reason for the change, for example in an accompanying note. This can improve the user's understanding and will likely improve conformance.

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What do auditors like to see?

- Complete records
- Records readily available
- Corrective actions for deviations are taken and recorded
- Sign-off where appropriate
- No notes on the documents unless they are relevant
- Dated documents and records
- Well-organized and legible documents and records

v. Keep It Simple
Use common language and words easily understood by those who will use the documents and records. Avoid acronyms. Be straight forward; for example, use logical steps, numbering or bullet points.

vi. Have Material Reviewed
Ask users of the material to review it to ensure understanding.

B. Consistency

Although flexibility is important and you may be using a variety of different types of documents and records in your facility, standard conventions can help users and auditors quickly identify and read them. Some techniques to consider:

i. Format Consistently
Use the same format for similar documents. For example, have the title, date, and page number in the same place on all documents and forms. Headers and footers are useful for this.

ii. Track Consistently
Use a consistent method for tracking documents. Link written procedures, training documents and record forms for each program with a simple tracking or numbering system.

C. Document and Record Control

You should ensure that only current documents and records are being used in your facility. Some techniques to help:

i. Acknowledge Receipt
Have a method (e.g., signing, dating, and returning) to confirm that the new documents are received and understood by those who will use them.

ii. Removal of Old Documents
Have a method to collect old documents as new ones are developed. The HACCP coordinator can keep these on file, but, to avoid confusion, outdated documents and records should be removed from circulation.

D. Consolidation

For efficiencies, you could weave together HACCP documents and records and those from other programs.

i. Combine Records From Different Programs

When similar tasks are to be completed by the same person or generally at the same time, merge the documents. For example, a form could include sections for recording HACCP-related monitoring and sections for workplace safety checks. Such integration may be useful in areas such as Environmental Control prerequisite programs.

E. Authority and Authenticity

You could implement measures to indicate management approval and authenticity.

i. Get Approval

Have a place on your documents for management to sign indicating approval. This will give documents authority and may improve conformance by those using the materials. It may also prevent overlap or gaps as management oversees various operations.

ii. Authenticate Originals

Have a method to identify documents and record forms as originals. For example, include a coloured company logo or plant identification to avoid inappropriate copying or rewriting of information.

4. RETENTION OF DOCUMENTS AND RECORDS

It is a good practice to retain documents and records for at least the shelf life of the product, preferably longer. In cases where the product is shelf-stable (e.g., canned goods), you should set a document and record retention time of at least three years. At a minimum, all documents and records should be kept for at least 18 months for audit purposes. Any applicable legislation, regulations, or customer requirements may require a longer retention time.

Using a computer for HACCP

The prerequisite programs and HACCP plans can be kept electronically; however, it is critical to keep a hard copy in case of system failure. Part of the Certification Audit may require you to send examples of your prerequisite programs, HACCP plans and blank copies of your record forms to the certifying body for review.

Other auditors may come to your facility and need to see the written HACCP system. A computer may not be available for such an audit; therefore, a hard copy should be made available.

Using computer software can help decrease the amount of paperwork. Remember, that if the software is doing the monitoring, you will still need to perform the appropriate corrective actions and verification.

Figure 5.2 Example GMP Program Monitoring Checklist

Week of ____________	✓= satisfactory X = deviation	Describe & record corrective action

Standard	M	T	W	T	F	Comments	Initials
01.1 Personnel do not eat, use tobacco, drink, chew gum, spit, sneeze or cough over food or food contact surfaces, or perform any other potentially hazardous activities in areas where food or packaging materials are being processed, handled or stored. Objects, such as jewelry, that may cause contamination are removed or are suitably covered prior to starting work duties. Personnel maintain an appropriate degree of personal cleanliness.							
01.2 Hand washing is performed with warm potable water, soap and hygienic drying apparatus upon entering food processing and handling areas; prior to handling food, ingredients, packaging materials or food contact surfaces; following breaks or use of toilet facilities; and when hands become contaminated.							
01.3 Clothing, footwear and headwear are worn by personnel and visitors in processing and handling areas. Clothing, footwear and headwear used in the establishment are stored and handled in a manner that prevents or minimizes contamination of food, ingredients, packaging materials and food contact surfaces.							
01.4 Clothing, utensils and equipment used in the establishment are stored and handled in a manner that prevents or minimizes contamination of food, ingredients, packaging materials and food contact surfaces.							
01.5 Personnel having open cuts or wounds do not handle exposed food, ingredients, packaging materials or food contact surfaces unless measures are taken to prevent direct or indirect contamination of food. When injuries or wounds occur during food processing or handling activities, measures are taken to ensure that suspect food, ingredient and packaging materials are disposed of and food contact surfaces are cleaned and sanitized.							
01.6 Personnel known or suspected to be suffering from or to be carriers of a disease transmissible through food do not enter any food processing or handling areas, or handle food, ingredients, packaging materials or food contact surfaces without taking measures to prevent contamination.							
01.7 Access of persons is controlled to prevent or minimize contamination of food, ingredients, packaging materials and food contact surfaces. Personnel follow designated traffic patterns to prevent or minimize contamination of food, ingredients, packaging materials and food contact surfaces.							
01.8 Chemicals are mixed in clean, correctly labelled containers, in the correct concentrations, and are dispensed and handled only by authorized and properly trained personnel. Chemicals are suitable for use within a food processing establishment and when used correctly do not present a food safety hazard.							
01.9 Chemicals used during operations are handled and stored in a manner that prevents contamination of food, ingredients, packaging materials and food contact surfaces. Chemicals used during operations are in appropriately labelled containers or dispensers.							

Monitored By:____________________ Date:__________________

(Note: this form does not realistically include enough room to record all potential deviations and corrective actions for all nine standards for a week. In this case you would need to develop a separate form to record deviations and corrective actions.)

IN SUMMARY

After reading this chapter, you should be able to provide answers to the following questions:

1. What is the difference between a document and a record?
2. Why are records so important?
3. How long do I need to keep records?

Points to remember

- Documents can change; records cannot.
- Keep records for the shelf life of the product or for at least 18 months for auditing purposes.
- Limit the number of monitoring records you create by using efficient record forms.

CHAPTER SIX

Implementing Prerequisite Programs

Key Points in Chapter 6

The step-by-step instructions in this chapter will help you develop and implement the requirements of the 57 prerequisite program standards, and allow you to fulfill the prerequisite program portion of the *HACCP Advantage* program.

The prerequisite program section of the *HACCP Advantage* has four program groups: Control Programs, Training, Operational Controls and Environmental Controls.

There is a linkage between standards in different prerequisite program groups.

There is information provided to support each individual prerequisite program standard.

Implementing each prerequisite program follows a clear process.

Following implementation, all prerequisite programs must be monitored for conformance over time.

Implementing Prerequisite Programs

1. HOW ARE THE PREREQUISITE PROGRAM STANDARDS ORGANIZED?

The prerequisite program standards are divided into four groups:

- Control Programs
- Training
- Operational Controls
- Environmental Controls.

Each group is divided into subgroups, based on the types of hazards it is meant to control.

A. Control Programs

Standards in the Control Programs outline the required written control programs that you need to develop and maintain. This group is also referred to as the P (for "program") group.

The written control programs required in the Control Programs group are:

- Good Manufacturing Practices
- Shipping, Receiving, and Storage
- Sanitation
- Equipment Maintenance
- Pest Control
- Recall
- Water Safety.

Each of the above written Control Programs has one standard in the *HACCP Advantage Program Manual*, with the exception of Water Safety, which has two (See Figure 6.2).

Meeting the standards in the Control Programs group requires developing and writing the above Control Programs. The end results are written programs; no implementation in the facility is required to meet these standards. When developing and writing these Control Programs, you should ensure that any specific requirements identified in the Operational Controls group are included. Training employees on these Control Programs is done through standards in the Training group. Implementation of these written control programs is done through standards in the Operational Controls group.

Proper development of the Control Programs group is crucial; failure to write effective *control programs* will negatively affect standards in both the Training group and Operational Controls group. Remember, the written control programs are the basis for the Training and Operational Controls standards.

B. Training

Standards in the Training group outline the requirements for all food safety-related employee-training programs. In order for the written control programs to work as designed, employees responsible for the tasks outlined in the programs must be properly trained.

This group is also referred to as the T (for "training") group.

The training programs required in the Training group are:
- Good Manufacturing Practices
- Shipping, Receiving and Storage
- Sanitation
- Equipment Maintenance
- Pest Control
- Recall
- Water Safety
- Critical Control Point (CCP)
- Process Technology.

These standards ensure that employees receive general Good Manufacturing Practices (GMP) training as well as more specific training for particular employees that have a greater impact on food safety. For example, having a sanitation program and a sanitation team is not enough—that team needs to be trained on the specifics of the facility sanitation program and how to implement it effectively without causing cross-contamination. Failure to do so could result in improperly cleaned equipment or a dangerous chemical accident.

Except for the last two, the Training standards match the Control Programs standards (this link is explained in the next section). The written program for CCPs is developed through the HACCP plan, not through prerequisite programs. Employees need to be properly trained regarding HACCP as well as any duties associated with monitoring and verifying CCPs. Process technology training refers to the specialized need for training on the use of specialized equipment that if not used properly could result in a food safety hazard. Examples of this type of equipment include retorts, heat exchangers and high-speed milling equipment.

C. Operational Controls

The standards in the Operational Controls group ensure that the programs developed in the Control Programs group are implemented as intended. This group is also referred to as the O (for "operations") group.

Operational controls are required for:
- Good Manufacturing Practices
- Shipping, Receiving, and Storage
- Sanitation
- Equipment Maintenance
- Pest Control
- Recall
- Water Safety

Some of the above categories include several standards to address specific food safety issues that warrant individual control (e.g., Shipping, Receiving, and Storage includes ten standards, such as O2.1 Conveyance Vehicles and O2.6 Allergen Control). Other categories include only one standard that is designed to address a broader food safety issue (e.g., O5.1 Pest Control)(See Figure 6.2).

In the Control Programs group there is a requirement for a written sanitation program (P3.1). The goal of this program is to develop policies and procedures for a clean facility. The goal of the sanitation standards in the Operational Controls section (O3.1 and O3.2) is to perform these policies and procedures as written.

D. Environmental Controls

The Environmental Controls group outlines the requirements that the premises, facility and equipment must meet to create a safe and suitable food processing environment. These standards are not related to people or their actions. This group is referred to as the E (for "environmental") group.

The Environmental Controls group includes standards that pertain to:
- Establishment location and construction
- Establishment design
- Establishment interior
- Equipment
- Water supply

A safe and suitable environment is one that does not provide opportunities for cross-contamination. Things like condensation, poor waste handling facilities, rusty equipment, open or broken windows, a cracked foundation, or a leaky roof can all lead to cross-contamination and potential food safety hazards.

In some cases, it may be costly to perform repairs or make replacements. If an interim control can mitigate the risk from the hazard, then it may be a less costly option. However, these are temporary solutions at best; the root problem must eventually be resolved.

The difficulty of implementation of these standards will depend on the existing condition of the premises, facility and equipment. It will be easier to meet these standards in a brand new facility that was designed with food safety in mind than in an older facility that requires extensive repairs, additions, or renovations.

technical**terms**

An **interim control** can be a task performed by an employee, usually on a short-term basis, to control a hazard. For example, an employee may squeegee or mop a floor to control pooling water from a poorly drained floor. An interim control can also be a scheduling of activities to prevent a hazard if physical controls are not available. For example, raw and cooked products could be produced on different days in the same area, rather than in separate areas.

2. THE GROUPS ARE LINKED

Standards in three of the four groups are related and linked. The numbering format of the standards is designed to facilitate easy reference and cross-reference, and to link Control Program standards to the corresponding Training and Operational Control standards.

For example, sanitation requirements are included in three separate but linked standards:

- A written sanitation program is developed and documented.
- Sanitation training is delivered to employees.
- Sanitation activities are performed, monitored and recorded.

These three sanitation requirements are controlled by standards in three of the four prerequisite program groups. The numbering system links these corresponding standards by having the same number prior to the decimal. The sanitation control program standard is P3.1, the sanitation training standard is T3.1, and the sanitation operational controls are O3.1 and O3.2.

Figure 6.1: Linkage between Prerequisite Program Groups

P3 Sanitation	**T3 Sanitation**	**0.3 Sanitation**
P3.1 Sanitation Program	T3.1 Sanitation Training	03.1 Cleaning and Sanitizing
		03.2 Pre-operational Assessment

The Environmental Controls group does not directly link to the other three groups and thus the numbering system does not follow through for that section. Table 6.1 displays all of the prerequisite standards with their corresponding numbering.

Figure 6.2: Prerequisite Program Groups

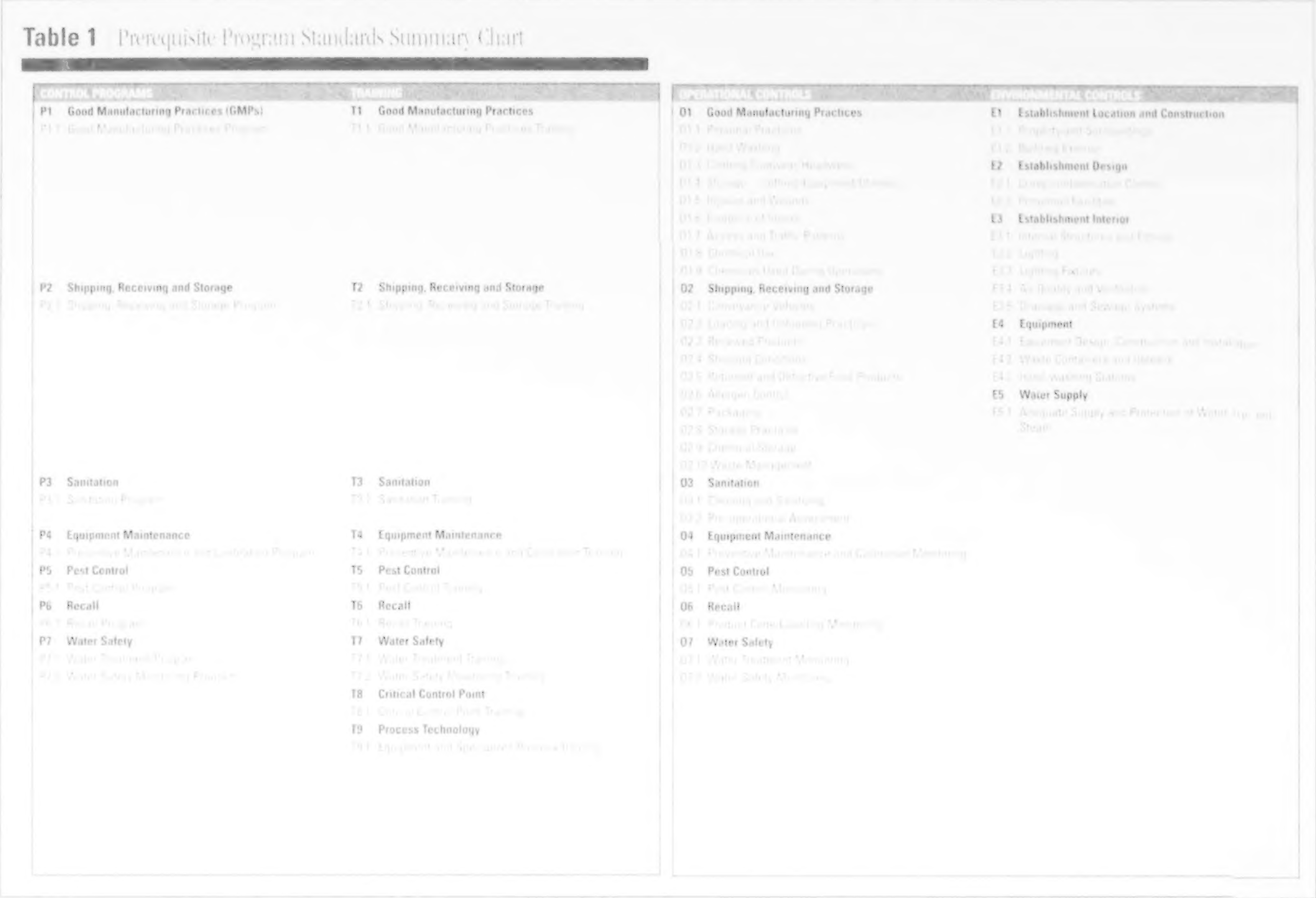


Table 1 Prerequisite Program Standards Summary Chart

CONTROL PROGRAMS	TRAINING
P1 Good Manufacturing Practices (GMPs)	**T1 Good Manufacturing Practices**
P1.1 Good Manufacturing Practices Program	T1.1 Good Manufacturing Practices Training
P2 Shipping, Receiving and Storage	**T2 Shipping, Receiving and Storage**
P2.1 Shipping, Receiving and Storage Program	T2.1 Shipping, Receiving and Storage Training
P3 Sanitation	**T3 Sanitation**
P3.1 Sanitation Program	T3.1 Sanitation Training
P4 Equipment Maintenance	**T4 Equipment Maintenance**
P4.1 Preventive Maintenance and Calibration Program	T4.1 Preventive Maintenance and Calibration Training
P5 Pest Control	**T5 Pest Control**
P5.1 Pest Control Program	T5.1 Pest Control Training
P6 Recall	**T6 Recall**
P6.1 Recall Program	T6.1 Recall Training
P7 Water Safety	**T7 Water Safety**
P7.1 Water Treatment Program	T7.1 Water Treatment Training
P7.2 Water Safety Monitoring Program	T7.2 Water Safety Monitoring Training
	T8 Critical Control Point
	T8.1 Critical Control Point Training
	T9 Process Technology
	T9.1 Equipment and Specialized Process Training

OPERATIONAL CONTROLS

O1 Good Manufacturing Practices
O1.1 Personal Practices
O1.2 Hand Washing
O1.3 Clothing, Footwear, Headwear
O1.4 Storage of Clothing/Equipment/Utensils
O1.5 Injuries and Wounds
O1.6 Evidence of Illness
O1.7 Access and Traffic Patterns
O1.8 Chemical Use
O1.9 Chemicals Used During Operations
O2 Shipping, Receiving and Storage
O2.1 Conveyance Vehicles
O2.2 Loading and Unloading Practices
O2.3 Received Products
O2.4 Shipping Conditions
O2.5 Returned and Defective Food Products
O2.6 Allergen Control
O2.7 Packaging
O2.8 Storage Practices
O2.9 Chemical Storage
O2.10 Waste Management
O3 Sanitation
O3.1 Cleaning and Sanitizing
O3.2 Pre-operational Assessment
O4 Equipment Maintenance
O4.1 Preventive Maintenance and Calibration Monitoring
O5 Pest Control
O5.1 Pest Control Monitoring
O6 Recall
O6.1 Product Code/Labelling Monitoring
O7 Water Safety
O7.1 Water Treatment Monitoring
O7.2 Water Safety Monitoring

ENVIRONMENTAL CONTROLS

E1 Establishment Location and Construction
E1.1 Property and Surroundings
E1.2 Building Exterior
E2 Establishment Design
E2.1 Cross-contamination Control
E2.2 Personnel Facilities
E3 Establishment Interior
E3.1 Internal Structures and Fittings
E3.2 Lighting
E3.3 Lighting Fixtures
E3.4 Air Quality and Ventilation
E3.5 Drainage and Sewage Systems
E4 Equipment
E4.1 Equipment Design, Construction and Installation
E4.2 Waste Containers and Utensils
E4.3 Hand-washing Stations
E5 Water Supply
E5.1 Adequate Supply and Protection of Water, Ice and Steam

Figure 6.2: Prerequisite Program Groups

Table 1 | Prerequisite Program Standards Summary Chart

CONTROL PROGRAMS	TRAINING	OPERATIONAL CONTROLS	ENVIRONMENTAL CONTROLS
P1 Good Manufacturing Practices (GMPs)	**T1 Good Manufacturing Practices**	**O1 Good Manufacturing Practices**	**E1 Establishment Location and Construction**
P1.1 Good Manufacturing Practices Program	T1.1 Good Manufacturing Practices Training	O1.1 Personal Practices	E1.1 Property and Surroundings
		O1.2 Hand Washing	E1.2 Building Exterior
		O1.3 Clothing/Footwear/Headwear	**E2 Establishment Design**
		O1.4 Storage – Clothing/Equipment/Utensils	E2.1 Cross-contamination Control
		O1.5 Injuries and Wounds	E2.2 Personnel Facilities
		O1.6 Evidence of Illness	**E3 Establishment Interior**
		O1.7 Access and Traffic Patterns	E3.1 Internal Structures and Fittings
		O1.8 Chemical Use	E3.2 Lighting
		O1.9 Chemicals Used During Operations	E3.3 Lighting Fixtures
P2 Shipping, Receiving and Storage	**T2 Shipping, Receiving and Storage**	**O2 Shipping, Receiving and Storage**	E3.4 Air Quality and Ventilation
P2.1 Shipping, Receiving and Storage Program	T2.1 Shipping, Receiving and Storage Training	O2.1 Conveyance Vehicles	E3.5 Drainage and Sewage Systems
		O2.2 Loading and Unloading Practices	**E4 Equipment**
		O2.3 Received Products	E4.1 Equipment Design, Construction and Installation
		O2.4 Shipping Conditions	E4.2 Waste Containers and Utensils
		O2.5 Returned and Defective Food Products	E4.3 Hand-washing Stations
		O2.6 Allergen Control	**E5 Water Supply**
		O2.7 Packaging	E5.1 Adequate Supply and Protection of Water, Ice, and Steam
		O2.8 Storage Practices	
		O2.9 Chemical Storage	
		O2.10 Waste Management	
P3 Sanitation	**T3 Sanitation**	**O3 Sanitation**	
P3.1 Sanitation Program	T3.1 Sanitation Training	O3.1 Cleaning and Sanitizing	
		O3.2 Pre-operational Assessment	
P4 Equipment Maintenance	**T4 Equipment Maintenance**	**O4 Equipment Maintenance**	
P4.1 Preventive Maintenance and Calibration Program	T4.1 Preventive Maintenance and Calibration Training	O4.1 Preventive Maintenance and Calibration Monitoring	
P5 Pest Control	**T5 Pest Control**	**O5 Pest Control**	
P5.1 Pest Control Program	T5.1 Pest Control Training	O5.1 Pest Control Monitoring	
P6 Recall	**T6 Recall**	**O6 Recall**	
P6.1 Recall Program	T6.1 Recall Training	O6.1 Product Code/Labelling Monitoring	
P7 Water Safety	**T7 Water Safety**	**O7 Water Safety**	
P7.1 Water Treatment Program	T7.1 Water Treatment Training	O7.1 Water Treatment Monitoring	
P7.2 Water Safety Monitoring Program	T7.2 Water Safety Monitoring Training	O7.2 Water Safety Monitoring	
	T8 Critical Control Point		
	T8.1 Critical Control Point Training		
	T9 Process Technology		
	T9.1 Equipment and Specialized Process Training		

3. WHAT INFORMATION SUPPORTS THE STANDARD?

In the "Prerequisite Programs" chapter of the *HACCP Advantage Program Manual*, each standards page includes more information then just the standard itself. The accompanying information for each standard gives you:

- The reason for the standard
- Suggestions for how to meet the standard
- Suggestions for how to ensure your facility is in conformance
- References to regulatory requirements where applicable.

The first letter of each standard's heading denotes the prerequisite group ("O" for Operational Controls in this case). The number following the letter denotes the subgroup ("1" or the first subgroup). The subgroup also has a specific title that is also listed in bold ("Good manufacturing Practices" here). The particular standard within the subgroup and its heading is listed to the right of the heading divider ("O1.6 Evidence of Illness" in this case).

Figure 6.3: Individual Prerequisite Program Standard Page Explanation

Each standard has five sections:

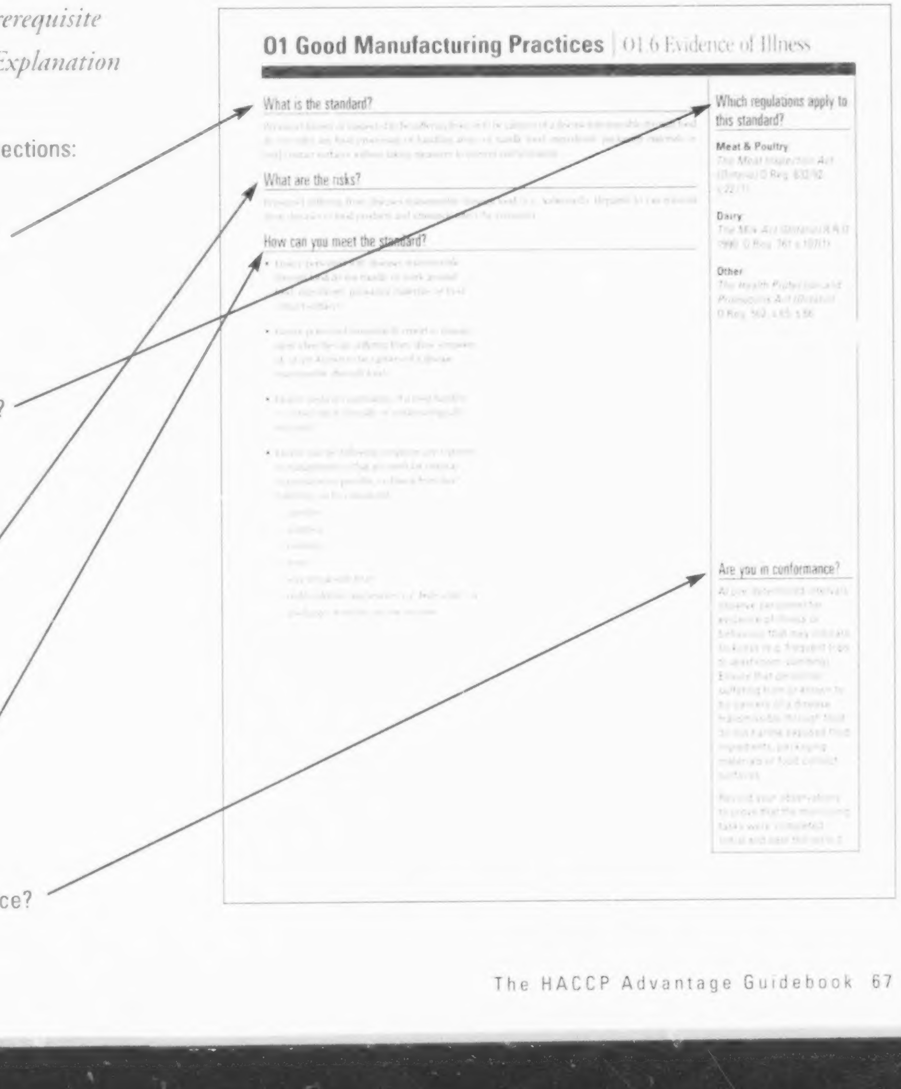
1. What is the standard?

2. Which regulations apply to this standard?

3. What are the risks?

4. How can you meet the standard?"

5. Are you in conformance?


O1 Good Manufacturing Practices | O1.6 Evidence of Illness
What is the standard?
What are the risks?
How can you meet the standard?
Which regulations apply to this standard?
Meat & Poultry
Dairy
Other
Are you in conformance?

technical**terms**

A **regulated commodity area** refers to certain commodities that currently are required to meet specific food safety-related legislation.

An explanation of each is provided below:

1. **What is the standard?**

The standard is stated here. It lays out the required food safety expectation in plain language. This is the most important part of the standards page and provides the basic criteria you must meet.

What is the standard?

Cleaning and sanitizing procedures are being performed as written in the Sanitation Program (P3.1) to protect the safety and suitability of food.

2. **Which regulations apply to this standard?**

Some commodity areas are regulated and have additional food safety expectations associated with a given standard. These regulatory references direct your attention to additional regulatory requirements. In many cases, compliance with the regulation(s) will encompass compliance with the prerequisite program standard.

Three regulations are referenced within this section. Two refer to very specific commodity groups while the third refers to all other processors. These groups and the associated regulation are:

- **Meat & Poultry:** all provincially licensed abattoirs are required to follow the *Meat Inspection Act* (Ontario) O.Reg. 632/92.
- **Dairy:** all provincially licensed dairy processors are required to follow the *Milk Act* (Ontario) O.Reg. 761.
- **All food processors:** all food processors and handlers (including restaurants and retail operations) are required to follow the *Health Protection and Promotion Act* (Ontario) O.Reg. 562.

Which regulations apply to this standard?

Meat & Poultry:
The Meat Inspection Act (Ontario) O Reg. 632/92, s22(1)

Dairy:
The Milk Act (Ontario) R.R.O. 1990. O.Reg. 761.s.107(2), O.Reg. 753.s.9

Other:
The Health Protection and Promotions Act (Ontario) O.Reg. 562, s.65; s.65; s.66

3. What are the risks?

This section explains why the standard exists to maximize food safety and what hazard(s) it is meant to control. When you understand the reasoning behind a standard, it is easier to ensure the standard is met.

What are the risks?

Personnel suffering from diseases transmissible through food (e.g. *Salmonella*, Hepatitis A) can transmit these diseases to food products and ultimately infect the consumer.

4. How can you meet the standard?

This section outlines suggested control measures frequently used in the food processing industry. The items listed are suggestions, and are not the only ways to meet the standard, but are frequently the most effective ways. If you have a unique method to control a hazard that is not widely used, but you can prove it is effective in controlling the hazard, it will likely be acceptable. Just make sure you document it correctly and monitor the control mechanism like any other prerequisite program. In the example below you could meet prerequisite standard 'O1.6 Evidence of Illness' by meeting each of these bulleted items. Remember, in the Control Programs group, policies and procedures that include these requirements should have been developed. Additionally, the Training group should cover the training of employees on these policies and procedures. The Operational Controls group ensures that the policies and procedures are followed.

How can you meet the standard?

- Ensure personnel with diseases transmissible through food do not handle or work around food, ingredients, packaging materials or food contact surfaces.
- Ensure personnel immediately report to management when they are suffering from, show symptoms of, or are known to be carriers of a disease transmissible through food.
- Ensure medical examination of a food handler is carried out if clinically or epidemiologically indicated.
- Ensure that the following symptoms are reported to management so that any need for medical examination or possible exclusion from food handling can be considered:
  - jaundice;
  - diarrhea;
  - vomiting;
  - fever;
  - sore throat with fever;
  - visibly infected skin lesions (e.g. boils, cuts) or
  - discharges from the ear, eye or nose.

5. Are you in conformance?

This section outlines suggested monitoring procedures you can implement to ensure the standard is being met over a period of time. This is commonly referred to as monitoring and will be expanded upon later in this chapter. As in the previous section, these are only suggestions, and other methods may be used.

Are you in conformance?

At pre-determined intervals, observe personnel for evidence of illness or behaviour that may indicate sickness (e.g. frequent trips to washroom, vomiting). Ensure that personnel suffering from or known to be carriers of a disease transmissible through food do not handle exposed food, ingredients, packaging materials or food contact surfaces.

Record your observations to prove that the monitoring tasks were completed. Initial and date the record.

4. HOW TO IMPLEMENT THE PREREQUISITE PROGRAM STANDARDS

There are two stages to implementing each prerequisite program standard:

- Meeting the standard
- Monitoring how you meet the standard.

You will use slightly different approaches to meet the standards for each of the four prerequisite program groups, since each has a different intent and purpose. However, the principle of monitoring is the same, regardless of the group.

MEETING THE STANDARD

Four approaches are outlined below, one for the standards in each prerequisite program group.

A. Control Programs (P1–P7)

i. Read the Standard

Each standard in the Control Programs group outlines a requirement for a written control program.

ii. Assess Whether You Are Meeting the Standard Now

Do you currently have a written program to meet the standard you just read? Does your written program include everything described in the standard? For example, suppose you are considering a sanitation program as per P3.1 (Sanitation Program). To perform the gap analysis, examine what your facility currently has with respect to sanitation procedures. Do you have written procedures? If so, do they cover all areas and equipment of the facility? Do they include all the features required to meet the standard? These questions will need to be answered to determine the gap between what you are doing and what you need to be doing.

If your written program includes all of the items in the "How Can You Meet the Standard" section effectively, your written program is complete and you can proceed to "Monitoring How You Meet the Standard." If your written program is incomplete, proceed to the next step.

iii. Write a Control Program or Revise Your Existing Control Program

This involves writing the procedures, policies, and programs required to meet the standard. You should ensure that you include all the specifically itemized requirements outlined in the Operational Controls section.

Let's illustrate with the same example as above—sanitation program. This standard requires you to have a documented series of cleaning procedures for every piece of equipment and area within the facility. These procedures should include responsibility, frequency, methodology, record-keeping activities and all other items normally associated with a sanitation program.

Once your written control program is complete, you can proceed to "Monitoring How You Meet the Standard".

technical**terms**

A **gap analysis** is a comparison of what is required to what currently exists.

makingthe**grade**

Your last inspection report or audit can provide a good starting point for gap analysis. Be sure to review it.

B. Training (T1–T9)

i. Read the Standard

Each standard in the Training group outlines a requirement for a documented training program that is delivered to appropriate employees.

ii. Assess Whether You Are Meeting the Standard Now

Do you currently have a training program to meet the standard you just read? Does your training program include everything described in the standard? Have all your employees received the necessary training?

Let's consider our sanitation example, a sanitation training program as per T3.1 Sanitation Training. To perform the gap analysis, examine the current sanitation training material as well as whether employees are receiving this training. Does the sanitation training include all material in the written sanitation control program (P3.1)? Does the training include the basic information required for employees to do their job effectively? Have all sanitation employees received the sanitation training? Is refresher training provided at an appropriate frequency? Does a record of this training exist?

If your training program includes all of the items in "How Can You Meet the Standard" effectively, your training program is complete and you can proceed to "Deliver Training" below. If your training program is not complete, proceed to the next step.

iii. Develop Training Materials or Revise Your Existing Training Materials

This involves adapting your written control program into a training format. It is important to ensure that the components of your written control program are adequately explained to your employees. Training material can be developed for a variety of formats such as classroom sessions, one-on-one instruction, video, and/or self-study.

For example, sanitation training materials could include a manual outlining equipment-cleaning procedures, overhead slides illustrating the cleaning steps and a video on proper sanitizing techniques.

There are two occasions where training is required, but a corresponding written control program has not been developed as part of the prerequisite programs. These are T8.1 Critical Control Point Training and T9.1 Equipment and Specialized Process Training. The Critical Control Point Training will be based on the HACCP plan developed later. For Equipment and Specialized Process Training, develop training materials or enlist an off-site training program to ensure the competence of personnel responsible for operating specialized equipment or conducting specialized processes that may impact on food safety. This training program ensures that specialized pieces of equipment are properly operated and don't cause a contamination or food safety issue.

Once your training materials are complete, proceed to the next step.

iv. Deliver Training

Deliver the training you have developed to the appropriate employees.

Using our example, sanitation training materials may be delivered through a classroom lecture on the basics of cleaning and sanitizing for all employees and a hands-on demonstration of proper cleaning techniques and steps for individual pieces of equipment.

Once training has been delivered to appropriate employees, you can proceed to "Record Training Activities."

v. Record Training Activities

You must keep an accurate record of all training activities. This information will be required to prove you are meeting the prerequisite program standard. Training records should include the name and signature or initials of trainees, name of the trainer, date that training was delivered, and the content of the training.

Once all of your training has been recorded, you can proceed to "Monitoring How You Meet the Standard".

C. Operational Controls (O1–O7)

i. Read the Standard

Each standard in the Operational Controls group outlines rules and requirements that must be followed to ensure the programs written in the Control Programs group are implemented as intended. Commonly these rules and requirements are elaborated upon in "How Can You Meet the Standard."

ii. Assess Whether You Are Meeting the Standard Now

Are employees currently following the rules and requirements to meet the standard you just read?

Let's consider our sanitation example. Sanitation Operational Control as per O3.1 Cleaning and Sanitizing requires that all elements of the written sanitation program (P3.1) be implemented and completed as written. To perform the gap analysis, check to see whether trained sanitation employees are following the written sanitation program.

Using another example, O2.1 Conveyance Vehicles requires all food conveyance vehicles to be suitable and to permit effective sanitation and pest control. Additionally, incoming and outgoing vehicles are assessed before and during unloading and loading. To perform the gap analysis, check to see that food conveyance vehicles are suitable and that trained shipping and receiving employees are examining incoming and outgoing conveyance vehicles.

If all rules and requirements in the standard are implemented and being followed, you can proceed to "Monitoring How You Meet the Standard". If the rules and requirements are not yet being followed, proceed to the next step.

iii. Implement the Rules and Requirements

Put into practice the rules and requirements stated in the written program. Remember, the specific individual requirements listed in O1 Good Manufacturing Practices and O2 Shipping and Receiving should be part of your written program.

Again returning to the sanitation example, O3.1 Cleaning and Sanitizing requires that the written sanitation program be fully implemented in the facility.

Once all of the rules and requirements of the control program have been implemented, you can proceed to "Monitoring How You Meet the Standard".

D. Environmental Controls (E1–E5)

i. Read the Standard

Each standard in the Environmental Controls group outlines requirements for the premises, facility or equipment that are required to create a safe and suitable food processing environment.

ii. Assess Whether You Are Meeting the Standard Now

Are your premises, facility and equipment meeting the required design or construction standard? For example, are your lighting fixtures adequately protected against breakage (E3.3 Lighting Fixtures)? Do you have a safe and suitable food processing environment?

If your premises, facility, and equipment meet the standard, you can proceed to "Monitoring How You Meet the Standard" below. If modifications are required, proceed to the next step.

iii. Make Any Necessary Changes

It is possible that after your gap analysis you may realize some sort of facility upgrade, renovation or significant equipment maintenance may be the best way to meet the standard. If this is the case, you may need to take short-term measures to ensure the standard is being met until you can make the necessary changes. Remember, though, that short-term fixes are just that—short-term. Ensure that you develop an implementation plan for capital upgrades and equipment maintenance. Get management buy-in and agreement.

5. MONITORING HOW YOU MEET THE STANDARD

Monitoring is the process of checking at a predetermined frequency that the prerequisite programs are operating effectively and have the desired outcome.

When deciding what to include and document in your monitoring procedures, you should consider the three Ws and the one H.

Who? What? When? How?

In addition to the Ws and an H, you need to also consider corrective actions and records.

i. Who?

"Who" defines the actual job position or person with whom the responsibility to perform the monitoring lies. This may be a person but more often it is listed as a position (e.g., the line supervisor or the packing room operator), which is referred to as the "monitor." The monitor does not have to be dedicated to the prerequisite programs. More often, he or she performs these monitoring tasks as a small subset of regular duties.

ii. What?

"What" defines the monitoring task to be completed. Use a simple sentence to state the goal of the monitoring task and its expected outcome.

iii. When?

"When" defines the time and/or frequency at which the monitor must perform the monitoring task. The frequency of monitoring will vary greatly from task to task and should be based on relevant risk, and the feasibility to perform the task at the stated frequency. For example, you might monitor cooler temperatures daily but dry storage temperatures weekly.

iv. How?

"How" defines how the monitoring task is performed. This should be a step-by-step procedure that guides the monitor and explains how the monitoring task is performed. This should include all steps and references to all required equipment, such as thermometers or testing swabs, as well as records.

v. Corrective Actions

Corrective actions define the series of steps the monitor is to follow should the monitoring task indicate a deviation in meeting the prerequisite program standard. It is difficult to predict every problem that may occur, let alone develop corrective actions for each. Therefore, corrective actions for prerequisite programs will often include a generic series of steps that requires the monitor or someone with appropriate authority to make an on-the-spot decision as to the method to best get the deviation corrected (i.e., corrective action), thereby meeting the standard again.

Corrective actions must accomplish three things:

- Regain control of the hazard
- Control any affected product and determine the appropriate disposition
- Correct the root cause of the problem to prevent a reoccurrence of the deviation.

When determining the root cause of a problem, some experts suggest that you ask "Why?" five times until you know the real cause of the problem and then form suitable corrective actions. (However, it may take fewer or more questions to determine the root cause.)

For example, suppose that a pallet of chemical product is found in the raw meat cooler—a cross-contamination risk and a violation of the prerequisite program standards:

Q. Why was the pallet of chemicals in the food ingredient storage area?
A. Because the chemical storage room could not be accessed.

Q. Why could the chemical storage room not be accessed?
A. Because the chemical storage room door was blocked with recently received packing materials.

Q. Why were the packing materials placed in front of the door?
A. Because the night-time incoming materials receiver was ill and the fill-in personnel did not know where to store some items. The chemical storage room was convenient and is right next to the receiving area.

Q. Why did the fill-in personnel not know where to store the chemicals?
A. Because he has never received shipping and receiving training.

Q. Why did he not receive the training?
A. Because that training had been given to daytime personnel and the lone night receiver only.

In this instance, the facility could take the following actions:

1. **Regain control of the hazard**—Immediately move the chemicals from the raw meat cooler to the chemical storage room. Remove the packaging materials that are blocking the chemical storage room door to the proper packaging storage area.

2. **Control affected product and determine disposition**—Examine all food ingredients that were on or near the chemicals while they were in the room. Is there any evidence of contamination? Leaking? Odours? Off-colour? Give an appropriate product disposition or action decision: release, rework or disposal.

3. **Correct the root cause**—There are a number of actions the facility could take that would complete, or in part, correct the root cause. Not all may be feasible in all cases.
    - Retrain all normal and backup shipping and receiving personnel on all proper receiving and storage procedures.
    - Set up a storage monitoring system where someone is responsible once or twice a day to ensure that no incompatible materials are stored together.
    - Expand the current chemical storage area or build another.
    - Adopt a policy that ensures the room doorway is always clear for reliable and easy access.
    - Have receiving personnel sign off on the correct storage of all hazardous materials.

Things to remember when performing corrective actions:

- Each corrective action completed should be properly recorded on the appropriate record and in the HACCP logbook if changes to the program were required.
- Every corrective action should be assigned a time frame for completion, at which time the corrective action is reviewed and closed if effective. If the corrective action is ineffective, new corrective actions will have to be devised and then implemented.
- Responsibility to complete each corrective action should be assigned to a specific individual or group of individuals. Someone needs to be responsible for its completion.

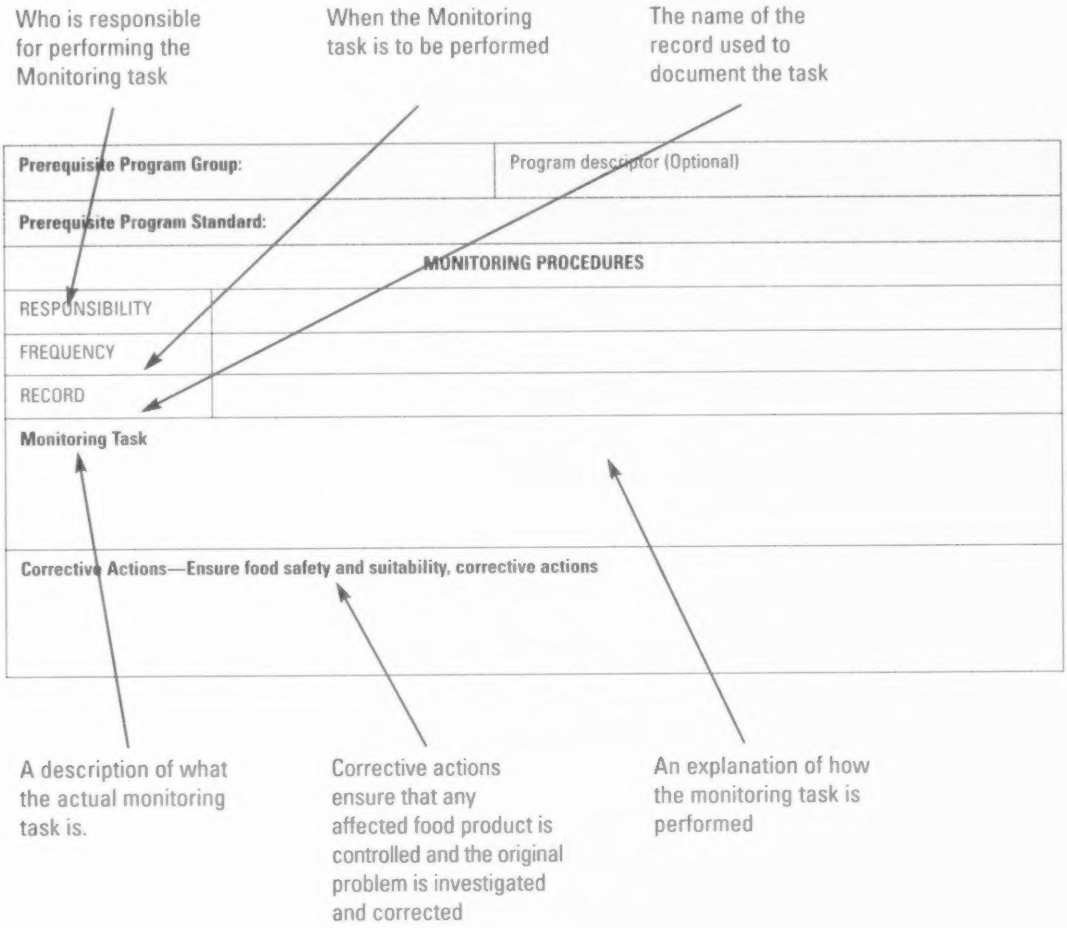
vi. Records

"Record" defines the actual physical checklist the monitor will use to record that the monitoring task was completed, as well as any corrective actions that might have been required. Whenever a record is completed, it must be signed or initialled by the monitor, who must also note the date and time the monitoring task was performed. Refer to Chapter 5 for more information.

6. PREREQUISITE PROGRAM EXAMPLES

In this section a standard from each of the four prerequisite program groups is discussed and an example is provided, showing how the documentation necessary for the standard could be captured.

Figure 6.4: Example Format for Documenting Prerequisite Program Monitoring Procedures



Who is responsible for performing the Monitoring task

When the Monitoring task is to be performed

The name of the record used to document the task

Prerequisite Program Group:	Program descriptor (Optional)
Prerequisite Program Standard:	
MONITORING PROCEDURES	
RESPONSIBILITY	
FREQUENCY	
RECORD	
Monitoring Task	
Corrective Actions—Ensure food safety and suitability, corrective actions	

A description of what the actual monitoring task is.

Corrective actions ensure that any affected food product is controlled and the original problem is investigated and corrected

An explanation of how the monitoring task is performed

This blank record provides a basic format for describing and documenting monitoring procedures and requirements. By no means must you follow this format, but monitoring procedures for each of the 57 prerequisite standards must be clearly documented. The forms provide examples of what to include in each area for a specific standard.

Here is an example of a basic GMP program. This example is not necessarily complete or comprehensive and should not be copied as is into your own program. You should develop your own GMPs; however many of the issues may be the same as those here.

Note the inclusion of the opening paragraph that states the scope and application of the program. Who does it apply to? Just employees? Visitors too, or do you want a separate policy for them? Contractors? Office staff? These are all additional items you should consider when authoring your GMP program.

These GMPs would become the formative document for the GMP control program (or prerequisite standard P1.1). Similar written control programs should be developed for each of the elements within the Control Program Group (P). Some of these may be much longer then others.

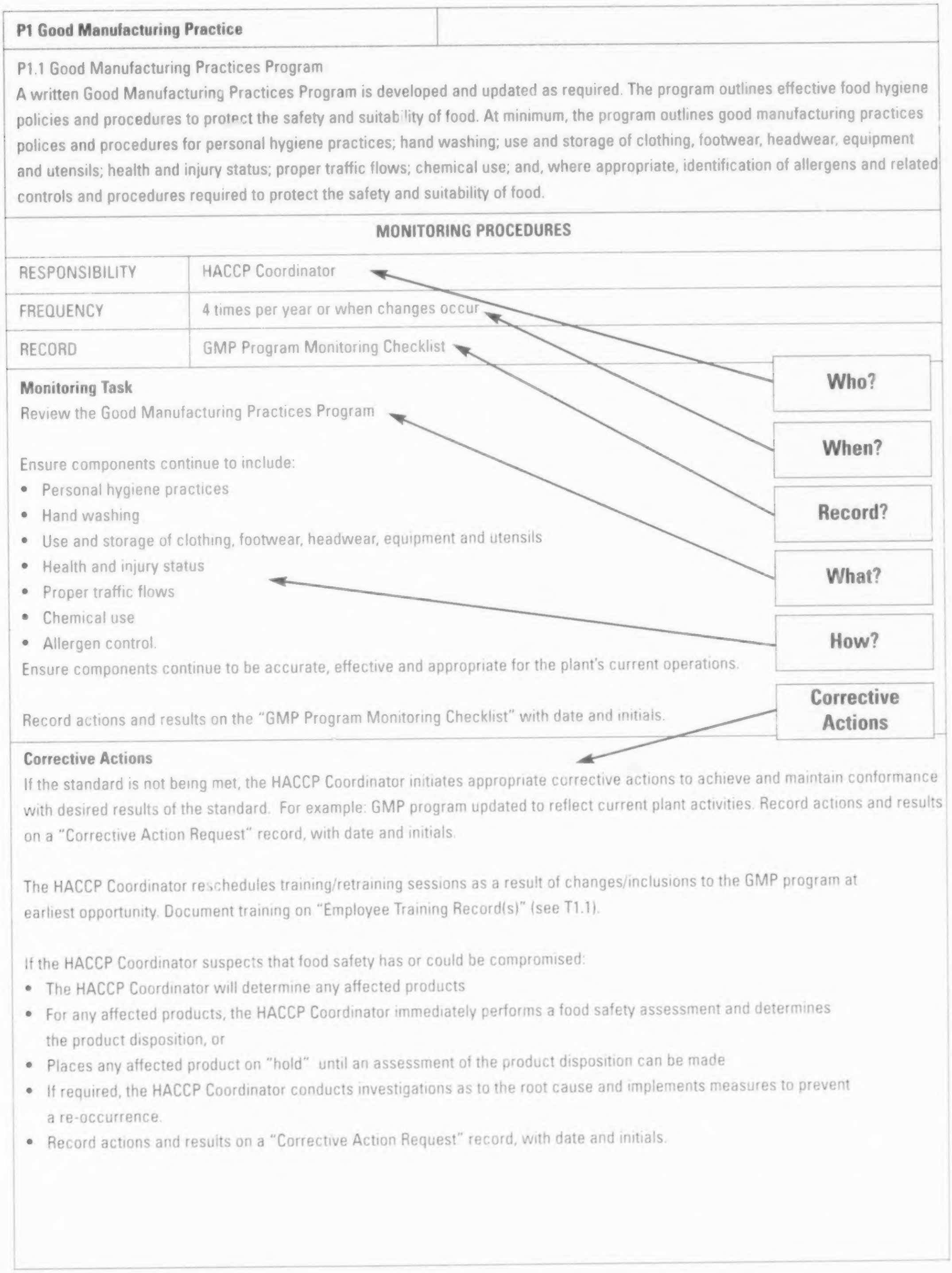
Figure 6.5: Example P1.1 Good Manufacturing Practices Program

Good Manufacturing Practices Program

It is the policy of Company XYZ to make product of the highest safety and quality. Everyone who works here is responsible for food safety. In order to always produce safe food and to comply with food regulations, each employee, visitor and contractor shall abide by the following rules.

	GMP Rules
1	No personnel shall bring food, medication, glass containers or any other prohibited items into the production area
2	Personnel shall refrain from chewing gum, using tobacco products or spitting in or around the production area.
3	Personnel shall not wear jewelry of any kind including necklaces, watches, broaches or rings. Nail polish, false eyelashes and nails are also not allowed
4	All personnel shall wash their hands when entering the production area, following use of personal welfare areas, after lunch and breaks, and after any action that may contaminate their hands (e.g., sneezing).
5	All personnel shall wear a suitable clean employee uniform at all times in the production area. Uniforms shall never be worn to and from work. All uniforms and footwear will be properly and cleanly stored when not in use.
6	Personnel with open cuts and wounds will not work in the production area without a secure watertight bandage covering the wound. All injuries occurring during production will be promptly reported.
7	Personnel known to be suffering from a disease transmissible through food will not enter any food processing areas or handle food, packaging or equipment.
8	All personnel shall stay within their respective work areas. Personnel handling raw product will not enter the cooked product area without changing their clothes and washing their hands.
9	All chemicals shall be mixed and dispensed only in clean, clearly labelled containers only by properly trained staff.
10	When chemicals are used during operation, all available measures will be taken to prevent product contamination including stopping the line, use of plastic, etc.

Figure 6.6: Example P1.1 Good Manufacturing Practices Program Monitoring Procedures


Who?
When?
Record?
What?
How?
Corrective Actions

P1 Good Manufacturing Practice	

P1.1 Good Manufacturing Practices Program
A written Good Manufacturing Practices Program is developed and updated as required. The program outlines effective food hygiene policies and procedures to protect the safety and suitability of food. At minimum, the program outlines good manufacturing practices polices and procedures for personal hygiene practices; hand washing; use and storage of clothing, footwear, headwear, equipment and utensils; health and injury status; proper traffic flows; chemical use; and, where appropriate, identification of allergens and related controls and procedures required to protect the safety and suitability of food.

MONITORING PROCEDURES

RESPONSIBILITY	HACCP Coordinator
FREQUENCY	4 times per year or when changes occur
RECORD	GMP Program Monitoring Checklist

Monitoring Task
Review the Good Manufacturing Practices Program

Ensure components continue to include:

- Personal hygiene practices
- Hand washing
- Use and storage of clothing, footwear, headwear, equipment and utensils
- Health and injury status
- Proper traffic flows
- Chemical use
- Allergen control.

Ensure components continue to be accurate, effective and appropriate for the plant's current operations.

Record actions and results on the "GMP Program Monitoring Checklist" with date and initials.

Corrective Actions
If the standard is not being met, the HACCP Coordinator initiates appropriate corrective actions to achieve and maintain conformance with desired results of the standard. For example: GMP program updated to reflect current plant activities. Record actions and results on a "Corrective Action Request" record, with date and initials.

The HACCP Coordinator reschedules training/retraining sessions as a result of changes/inclusions to the GMP program at earliest opportunity. Document training on "Employee Training Record(s)" (see T1.1).

If the HACCP Coordinator suspects that food safety has or could be compromised:

- The HACCP Coordinator will determine any affected products
- For any affected products, the HACCP Coordinator immediately performs a food safety assessment and determines the product disposition, or
- Places any affected product on "hold" until an assessment of the product disposition can be made
- If required, the HACCP Coordinator conducts investigations as to the root cause and implements measures to prevent a re-occurrence.
- Record actions and results on a "Corrective Action Request" record, with date and initials.

Below is an example of a training schedule and checklist. Please keep in mind that you don't necessarily need to follow this format; feel free to create your own. In this example you will notice there is no pest control training due to the fact that our fictional company employs an equally fictional pest control company to manage its pest control program. The HACCP co-ordinator must ensure that the pest control company employees are fully trained and additionally understand the elements of your company's HACCP system. This should be documented in their pest control program. In the example below you will see not every employee needs all training, just what is required for him or her to complete his or her job. However, all employees need GMP training.

Figure 6.7: Example Training Schedule and Checklist

Company XYZ HACCP Advantage Training Schedule and Checklist

All employees are responsible for food safety. Company XYZ has a policy that all employees must receive applicable food safety training as it relates to their work activities at the start of employment and at the frequencies outlined below.

Employee Divided by Work Area	Training Topic											
	GMP		Shipping/ Receiving		Sanitation		Recall		Water		HACCP	
	2 per year		1 per year		1 per year		1 per year		1 per year		4 per year	
	required	date completed	required	date completed	required	date completed	required	date completed	required	date completed	required	date completed
Production												
Ian	x	2/14/04	x								x	
Alicia	x	2/14/04	x								x	
Jeremy	x	2/14/04			x	5/19/04					x	
Lee	x	2/14/04									x	
Anne	x	2/14/04									x	
Clean-up												
Patrick	x				x	5/19/04					x	
Becky	x				x	5/19/04					x	
Management												
Sheri	x		x								x	
Alex	x						x		x		x	
QA												
Mike	x		x				x		x		x	
John	x				x		x		x		x	

Training schedule checked by: ______________________ **Date:** __________

Figure 6.8: Example T1.1 Good Manufacturing Practices Training Monitoring Procedures

T1.1 Good Manufacturing Practices

T.1.1 Good Manufacturing Practices Training
Good Manufacturing Practices Training is delivered and updated as required to ensure personnel involved in good manufacturing practices understand and are competent in the procedures necessary to protect the safety and suitability of food. Training is delivered at an adequate frequency to ensure personnel understanding remains current.

MONITORING PROCEDURES

RESPONSIBILITY	HACCP Coordinator
FREQUENCY	2 times per year or when changes occur
RECORD	Employee Training Records, GMP Training Program Checklist

Monitoring Task
Review the Good Manufacturing Practices Training

Ensure the training program is:
- Complete and accurate for the plant's operations
- Reflective of the current Good Manufacturing Practices program
- Delivered at the predetermined frequency to all appropriate employees.

Review the Employee Training Record(s) to ensure:
- That training records are properly completed

Record actions and results on "GMP Training Program Checklist" with date and initials

Corrective Actions
If the standard is not being met, the HACCP Coordinator initiates appropriate corrective actions to achieve and maintain conformance with desired results of the standard. For example: GMP training program updated to reflect current plant operations, schedule training/retraining sessions. Record actions and results on a "Corrective Action Request" record, with date and initials.

If HACCP Coordinator suspects that food safety has or could be compromised:
- The HACCP Coordinator will determine any affected products
- For any affected products, the HACCP Coordinator immediately performs a food safety assessment and determines the product disposition, or
- Places any affected product on "hold" until an assessment of the product disposition can be made
- If required, the HACCP Coordinator conducts investigations as to the root cause and implements measures to prevent a re-occurrence.
- Record actions and results on a "Corrective Action Request" record, with date and initials.

Figure 6.9: Example 01.2 Hand Washing Monitoring Procedure

P1 Good Manufacturing Practice	

01.2 Hand Washing
To prevent/minimize food contamination, effective hand washing is performed by all personnel who enter the food processing and handling areas or who handle food, ingredients, packaging materials or food contact surfaces. Hand washing is performed with warm potable water, soap, and hygienic drying apparatus upon entering food processing and handling areas, prior to handling food, ingredients, packaging materials, or food contact surfaces; following breaks or use of toilet facilities; and when hands become contaminated.

MONITORING PROCEDURES

RESPONSIBILITY	HACCP Coordinator, Production Facilitator
FREQUENCY	At minimum, twice per shft
RECORD	Daily GMP checklist

Monitoring Task
Confirmation that personnel are properly following hand washing procedures.

Visually observe production employees, visitors and maintenance personnel to ensure that they are following proper hand washing procedures upon entering food processing and handling areas; prior to handling food, ingredients, packaging materials, or food contact surfaces; following breaks or use of toilet facilities; and when hands become contaminated. Ensure hand washing is performed with warm potable water, soap, and hygienic drying apparatus.

Record observations on the "Daily GMP Checklist" with date and initials.

Corrective Actions
If the standard is not being met, the Production Facilitator initiates appropriate corrective actions to achieve and maintain conformance with desired result of the standard. For example:

- Coach employee on proper procedures
- Arrange for retraining
- Initiate repair/installation of hand washing stations to facilitate proper hand washing practices. If required, investigate cause and determine measures to prevent a reoccurrence.

Record actions and results on a "Corrective Action Request" record, with date and initials.

If the Production Facilitator suspects that food safety has or could be affected, inform the HACCP Coordinator. If HACCP Coordinator confirms that food safety has or could be compromised:

- The HACCP Coordinator will determine any affected products
- For any affected products, the HACCP Coordinator immediately performs a food safety assessment and determines the product disposition, or
- Places any affected product on "hold" until an assessment of the product disposition can be made
- If required, the HACCP Coordinator conducts investigations as to the root cause and implements measures to prevent a re-occurrence.
- Record actions and results on a "Corrective Action Request" record, with date and initials.

Figure 6.10: Example E2.2 Personnel Facilities Monitoring Procedures

E2 Establishment Design

E2.2 Personnel Facilities
Washrooms, change rooms and lunch and break area(s) are provided and maintained to ensure that personal hygiene can be maintained to protect the safety and suitability of food. Washrooms are equipped with adequate lighting and an adequate number of flush toilets and hand washing stations; are free of condensation, excess moisture or odours; and are designed to prevent or minimize contamination.

MONITORING PROCEDURES

RESPONSIBILITY	Maintenance Manager
FREQUENCY	At minimum monthly
RECORD	Building Inspection Record

Monitoring Task
Confirm that washrooms, change rooms, and lunch rooms are adequate for the number of personnel, properly equipped and maintained in good repair.

Observe that all washrooms, change rooms and lunchroom facilities have adequate lighting, have adequate and functioning ventilation, have adequate toilets and hand washing stations for all employees and that they are all in working order (e.g. toilets flush,). Rooms have no excessive odours and no condensation/moisture.

Records observations on the "Building Inspection Record" with date and initials.

Corrective Actions
If the standard is not being met, the Maintenance Manager initiates appropriate corrective actions to achieve and maintain conformance with desired result of the standard. For example,

- Initiates repair and/or arranges for outside service to repair item(s).
- Initiates cleaning of room/areas.
- Initiates ordering and installation of fixtures/items if required.
- Records corrective actions on "Corrective Action Request". Record with date and initials.

If the Maintenance Manager suspects that food safety has or could be affected, inform the HACCP Coordinator. If HACCP Coordinator confirms that food safety has or could be compromised:
- The HACCP Coordinator will determine any affected products
- For any affected products, the HACCP Coordinator immediately performs a food safety assessment and determines the product disposition, or
- Places any affected product on "hold" until an assessment of the product disposition can be made
- If required, the HACCP Coordinator conducts investigations as to the root cause and implements measures to prevent a re-occurrence
- Record actions and results on a "Corrective Action Request" record, with date and initials.

7. REVIEW

As mentioned earlier, there are two stages to implementing each prerequisite program standard:

- Meeting the standard
- Monitoring how you meet the standard.

The following table summarizes example items to conform to the 57 *HACCP Advantage* prerequisite program standards.

Table 6.1: Summary of Requirements to Meet and Monitor Each Prerequisite Program Standard

1. Meet the Standard			
Control Programs	**Training**	**Operational Controls**	**Environmental Controls**
• Develop the written program	• Develop the training program, including training materials and methods • Deliver the training	• Implement the written programs and conduct the required activities	• Ensure that premises, structures, equipment and water supply are appropriate
2. Monitor How You Meet the Standard			
Control Programs	**Training**	**Operational Controls**	**Environmental Controls**
• Review the written program	• Review the training program, including training materials and methods • Review training records	• Review records • Interview personnel • Observe actions • Test or inspect for effectiveness	• Inspect premises, facility structure, equipment and water supply

IN SUMMARY

After reading this chapter, you should be able to provide answers to the following questions:

1. What are prerequisite programs meant to control?
2. What accompanying information is included with each prerequisite program standard?
3. How are the first three groups (of four) of the prerequisite program standards related?
4. What types of things are important to include when documenting an individual prerequisite program standard?
5. What are the main goals of corrective actions?

Once you have completed your prerequisite programs you can move onto the next chapter. Implementing the *HACCP Advantage* HACCP plan.

Points to remember

- Prerequisite programs are an integral part of the *HACCP Advantage* and form the base for the HACCP plans themselves.
- Once your facility meets a prerequisite program standard, you must monitor that standard over time.
- Prerequisite programs control hazards associated with the facility environment and the facility personnel.
- When developing a prerequisite program consider *Who, What, When, How, Corrective Action, Record.*
- You may already be meeting many of the prerequisite program requirements; perform a gap analysis for each standard prior to developing your prerequisite programs.

CHAPTER SEVEN

Implementing HACCP Plans

Key Points in Chapter 7

Developing the HACCP plan section of the *HACCP Advantage* requires completing the eight HACCP plan forms.

The number of HACCP plans you will need to complete depends on the number and type of products your operation manufactures.

Training your employees for individual CCPs is critical.

Implementing HACCP Plans

1. THE HACCP PLAN FORMS

Once your prerequisite programs have been implemented, development and implementation of your HACCP plan(s) can begin. This is achieved using eight HACCP plan forms.

The eight HACCP plan forms are:
- Form #1: Product Description
- Form #2: Ingredients and Incoming Materials
- Form #3: Flow Diagram
- Form #4: Plant Schematic
- Form #5: Hazard Analysis and Critical Control Point Determination
- Form #6: Flow Diagram with Critical Control Points
- Form #7: Uncontrolled Hazards
- Form #8: HACCP Matrix.

2. HOW MANY HACCP PLANS WILL YOUR FACILITY NEED?

Each HACCP plan is unique to the facility and product group for which it is designed. The number of HACCP plans that you need for your facility depends on the different types of products manufactured and the different processes used to manufacture them. Quite often, products can be grouped into categories, and one HACCP plan can be created for each product category.

If you produce similar products through similar processing methods, and the end products have similar hazards, they may be grouped in one HACCP plan. But if you produce different products or products that have different food safety hazards associated with the manufacturing process or end product, these products must be grouped into separate HACCP plans.

For example, if you produce five different types of meatloaf, they can all be grouped under one HACCP plan if they all have the same types of food safety hazards. However, if you produce fully cooked meatloaf, dry cured pepperoni and raw boneless chicken breast, you need separate HACCP plans for each of these products since the process used to manufacture each one is different and the products have different hazards associated with them.

3. HOW TO IMPLEMENT YOUR HACCP PLAN

To implement a HACCP plan in your facility, you must complete the following eight forms in sequence.

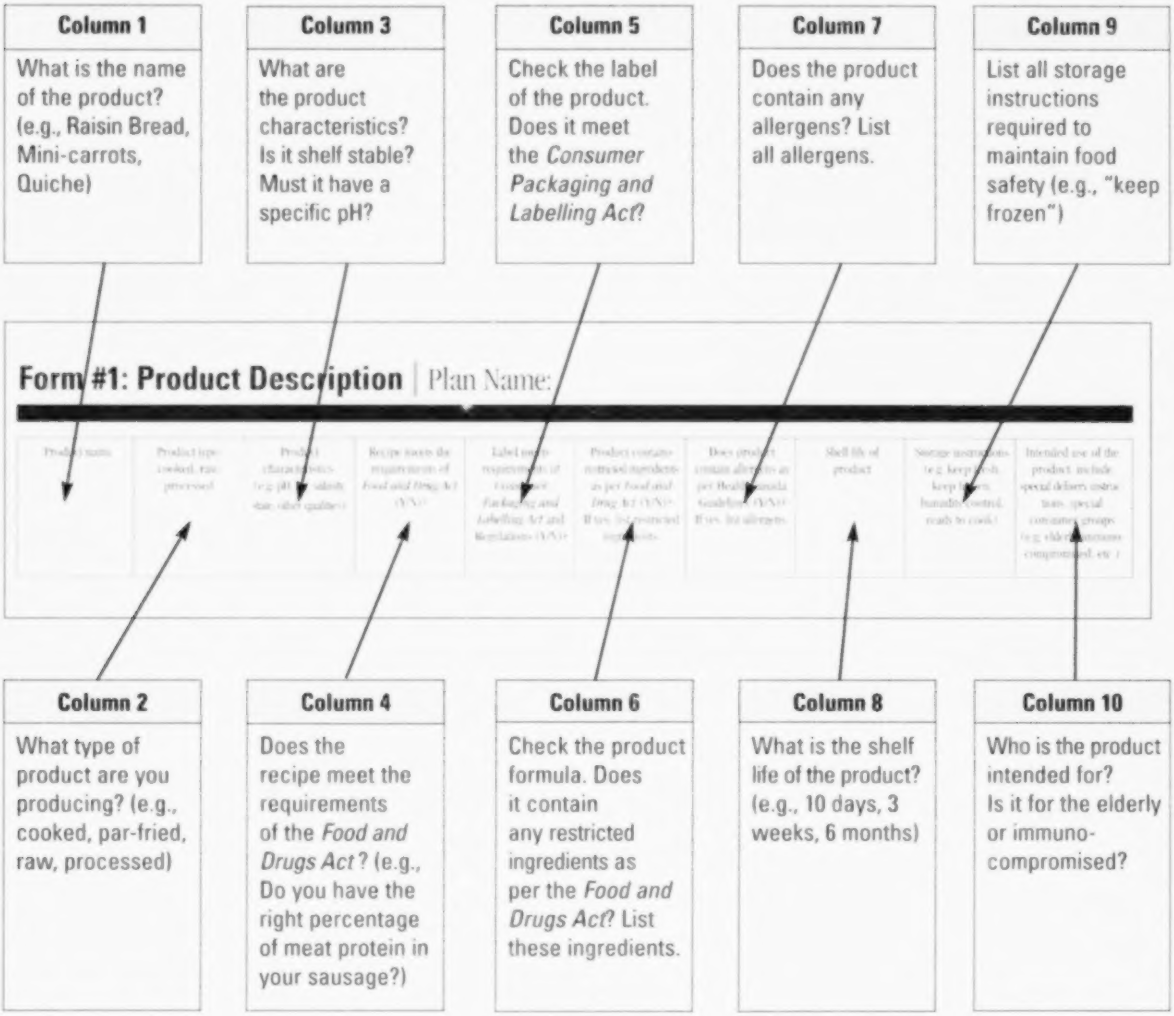
A. Form #1: Product Description

The information that is included on this form is:

- Product name
- Product type or state (e.g., cooked, raw, processed)
- Important product characteristics (e.g., pH, water activity, salinity)
- Conformance of the product recipe to the *Food and Drugs Act*
- Conformance of the product label to the *Consumer Packaging and Labelling Act and Regulations*
- Any restricted ingredients as per the *Food and Drugs Act*
- Any allergens as per Health Canada Guidelines
- Shelf life
- Storage and distribution controls
- Intended use and consumers of the product.

It is essential to list important product characteristics and ingredients as they are used to identify potential food safety hazards. For instance, allergens can present a serious health hazard to a specific segment of the population. The pH, A_w (water activity) and salinity of the product may affect the ability of micro-organisms to survive and grow.

Figure 7.1: HACCP Plan Form #1 Explanation



Column 1

What is the name of the product? (e.g., Raisin Bread, Mini-carrots, Quiche)

Column 2

What type of product are you producing? (e.g., cooked, par-fried, raw, processed)

Column 3

What are the product characteristics? Is it shelf stable? Must it have a specific pH?

Column 4

Does the recipe meet the requirements of the *Food and Drugs Act*? (e.g., Do you have the right percentage of meat protein in your sausage?)

Column 5

Check the label of the product. Does it meet the *Consumer Packaging and Labelling Act*?

Column 6

Check the product formula. Does it contain any restricted ingredients as per the *Food and Drugs Act*? List these ingredients.

Column 7

Does the product contain any allergens? List all allergens.

Column 8

What is the shelf life of the product? (e.g., 10 days, 3 weeks, 6 months)

Column 9

List all storage instructions required to maintain food safety (e.g., "keep frozen")

Column 10

Who is the product intended for? Is it for the elderly or immuno-compromised?

At the top of the form record the HACCP plan name. The HACCP plan name applies to all products that will be grouped into this particular plan, commonly the "category" of products manufactured. For example, it could be called "Meatloaf" or "Sausage."

1. Column One: Product name

In this column, write the name of each product that is produced under this HACCP plan. For example, if your facility makes one type of sausage, write the name of that one sausage product in this column. However, if your facility makes 20 different types of sausage, list all 20 sausage product names in this column. The rest of form #1 must be completed for each individual product name listed.

2. Column Two: Product type

In this column, write a description of the product type; for example, "raw" if your facility produces a raw sausage product. For ready-to-eat or cooked products you may insert "ready-to-eat" or "cooked."

3. Column Three: Product characteristics

Any product characteristics that could affect food safety must be recorded here.

Examples of important product characteristics:

- pH
- water activity (A_w)
- salinity

4. Column Four: Recipe meets the requirements of the *Food and Drugs Act*

All products sold in Canada are subject to the *Food and Drugs Act*. Therefore, you must ensure that your recipe complies with this Act. For more information, go to the Act Web site http://laws.justice.gc.ca/en/F-27/index.html. Once you have confirmed that your recipe meets the requirements of the Act, simply record "Yes."

5. Column Five: Label meets requirements of *Consumer Packaging and Labelling Act* and Regulations

The packaging of all products sold in Canada is subject to the C*onsumer Packaging and Labelling Act*. You must be certain that your product label meets the requirements of this Act. For more information go to the following Web site: http://laws.justice.gc.ca/en/C-38/37028.html. Once you have confirmed that your packaging meets the requirements of the Act, record "Yes."

6. Column Six: Restricted ingredients as per *Food and Drugs Act.*

Make sure you check the *Food and Drugs Act* regulations for restricted ingredients. Ensure that any restricted ingredients used to manufacture the product are recorded in this column.

7. Column Seven: Does product contain allergens as per Health Canada Guidelines?

Some of your products may contain allergenic ingredients. There are 10 important allergens to look for.

These are:

- **peanuts**
- **tree nuts** (almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pinenuts, pistachios, walnuts)
- **sesame seeds**
- **milk**
- **eggs**
- **fish and crustaceans** (e.g., crab, crayfish, lobster, shrimp)
- **shellfish** (e.g., clams, mussels, oysters, scallops)
- **soy products**
- **wheat**
- **sulphites.**

Record any allergenic ingredients used to manufacture your product in this column.

8. Column Eight: Shelf life of the product

Record the shelf life of each product in the HACCP plan. This might be one week, 30 days, six months, etc., depending on the product.

9. Column Nine: Storage instructions

The shelf life of the product may depend on how the consumer stores the product. Therefore, the storage instructions must be clear and include any special conditions, temperature or humidity requirements. For example, for a refrigerated product enter "Keep refrigerated" in this column.

technical**terms**

Allergen: A substance that causes some individuals to experience an immune response such as an allergic reaction. An allergy is a condition of reacting adversely to certain substances, especially particular foods, pollen and dust. Anaphylactic shock is a severe allergy where the immune system reacts to the allergen vigorously, causing harm to the allergic person.

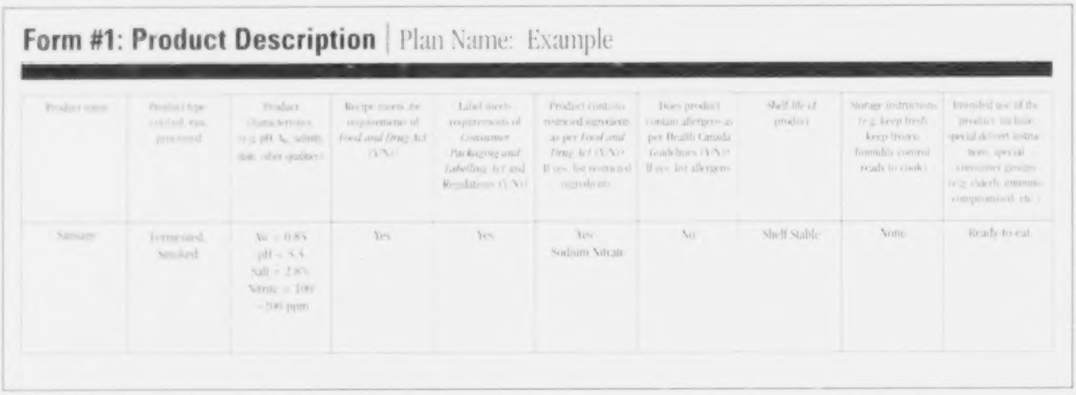
technical**terms**

A **hazard database** will provide a list of hazards associated with ingredients, packaging materials and processes. The CFIA has a hazard database for a number of incoming materials and processing steps.

10. Column Ten: Intended use of the product

In this column, you enter the intended use of the product. For example, if the product is intended for the general public, record "Retail." Extra precautions may be necessary when manufacturing products for infants or for the immuno-compromised, so these particular consumer groups must be identified in this column.

Form Figure 7.2: HACCP Plan Form #1 Example



Form #1: Product Description | Plan Name: Example

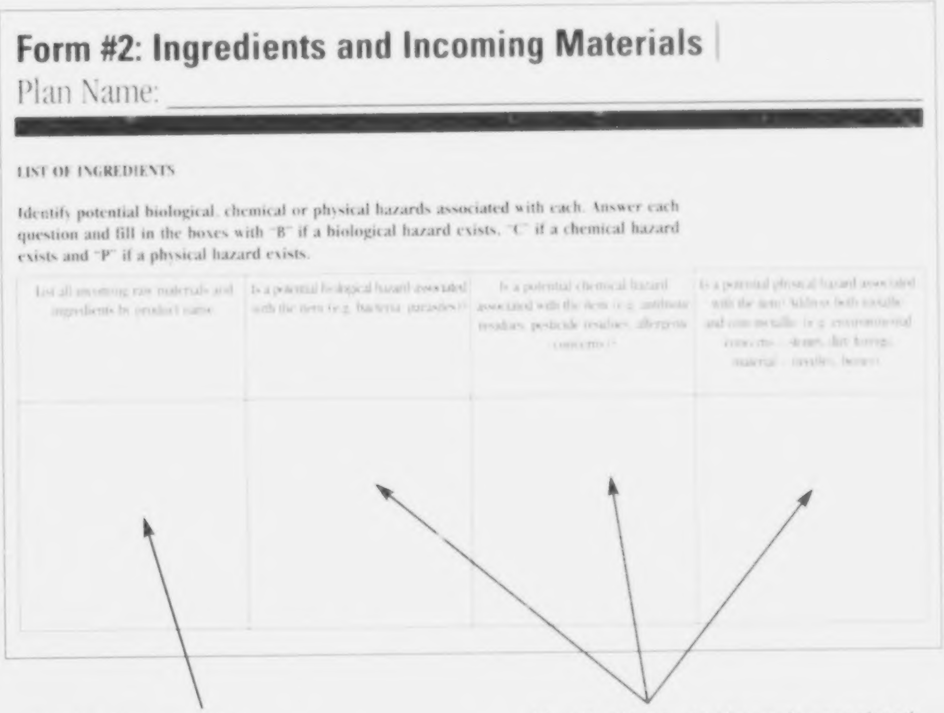
Product name	Product type (cooked, raw, processed)	Product Characteristics (e.g. pH, A_w, salinity, other qualities)	Recipe meets the requirements of *Food and Drug Act* (Y/N)	Label meets requirements of *Consumer Packaging and Labelling Act* and Regulations (Y/N)	Product contains restricted ingredients as per *Food and Drug Act* (Y/N)? If yes, list restricted ingredients	Does product contain allergens as per Health Canada Guidelines (Y/N)? If yes, list allergens	Shelf life of product	Storage instructions (e.g. keep fresh, keep frozen, humidity control, ready to cook)	Intended use of the product (include special delivery instructions, special consumer groups (e.g. elderly, immuno-compromised, etc.)
Sausage	Fermented, Smoked	A_w = 0.85 pH = 5.3 Salt = 2.8% Nitrite = 100 – 200 ppm	Yes	Yes	Yes Sodium Nitrate	No	Shelf Stable	None	Ready to eat

B. Form #2: Ingredients and Incoming Materials

Form #2 is used to list the ingredients and incoming materials (including processing aids and packaging materials) used to manufacture the products in this HACCP plan. In the Program Manual you will find that there are actually two Form #2s. The first is used to list all ingredients. The second is used to list all incoming materials including processing aids and packaging materials.

For each item you list on Form #2 you must identify biological, chemical and physical hazards associated with it.

Figure 7.3: HACCP Plan Form #2 Explanation



Form #2: Ingredients and Incoming Materials

Plan Name: ____________________

LIST OF INGREDIENTS

Identify potential biological, chemical or physical hazards associated with each. Answer each question and fill in the boxes with "B" if a biological hazard exists, "C" if a chemical hazard exists and "P" if a physical hazard exists.

List all incoming raw materials and ingredients by product name	Is a potential biological hazard associated with the item (e.g. bacteria, parasites)?	Is a potential chemical hazard associated with the item (e.g. antibiotic residues, pesticide residues, allergenic concerns)?	Is a potential physical hazard associated with the item? Address both metallic and non-metallic (e.g. environmental concerns – stones, dirt; foreign material – needles, bones)

In this column record:
All incoming ingredients, processing aids, and packaging materials that are used in the manufacturing of the product(s) in the HACCP plan.

Identify all potential hazards associated with each incoming ingredient, processing aid and packaging material. In these columns record B (biological), C (chemical), P (physical) as necessary.

Let's look at each of the four columns:

1. Column One: List all Incoming raw materials and ingredients by product name

Ensure that all of the incoming materials and ingredients used to manufacture products under this HACCP plan are listed in this column.

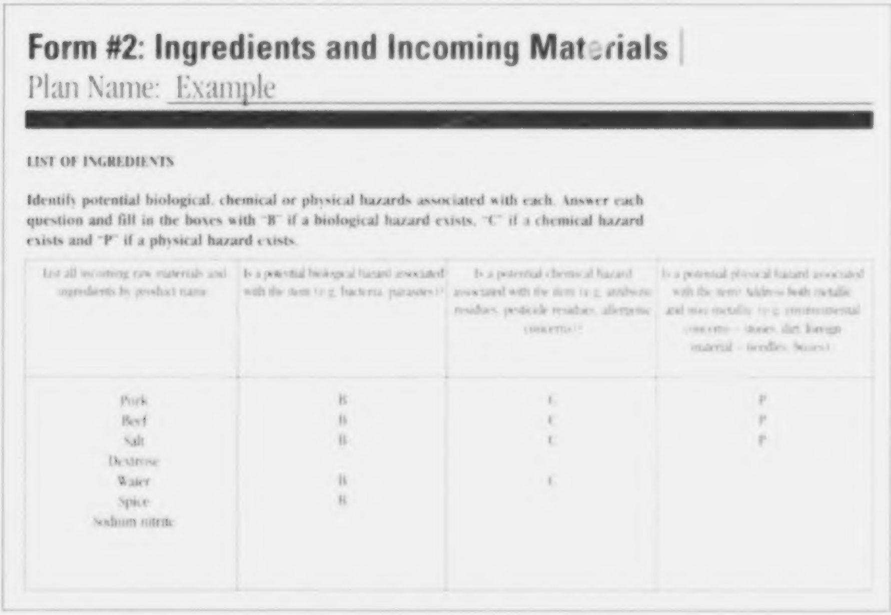
2. Column Two: Is a potential biological hazard associated with the item?

In this column record a "B" if there is a biological hazard associated with each item listed in column one. You may have to use a hazard database to determine the potential biological hazards associated with the incoming materials and ingredients.

3. **Column Three: Is a potential chemical hazard associated with the item?**
   In this column record a "C" if there is a chemical hazard associated with each item listed in column one. You may have to use a hazard database to determine the potential chemical hazards associated with the incoming materials and ingredients.

4. **Column Four: Is a potential physical hazard associated with the item?**
   In this column record a "P" if there is a physical hazard associated with each item listed in column one. You may have to use a hazard database to determine the potential physical hazards associated with the incoming materials and ingredients.

Figure 7.4: HACCP Plan Form #2 Example



Form #2: Ingredients and Incoming Materials

Plan Name: Example

LIST OF INGREDIENTS

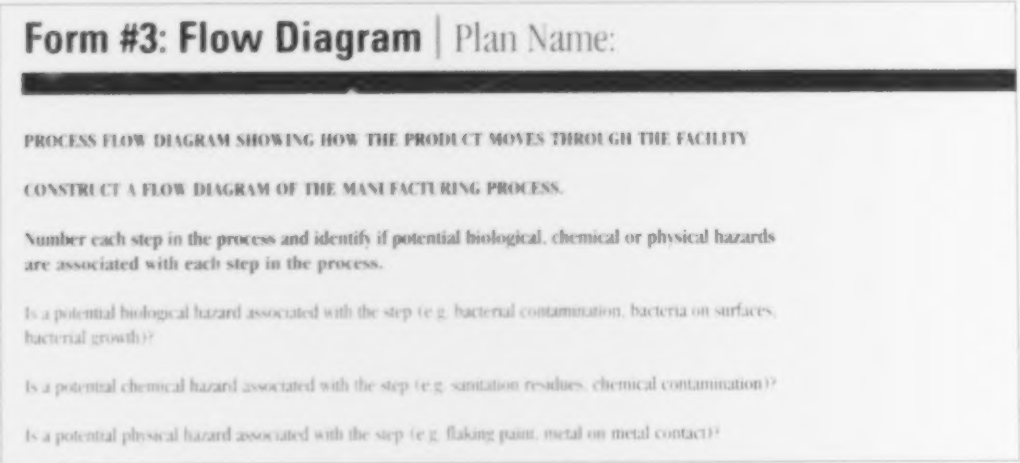
Identify potential biological, chemical or physical hazards associated with each. Answer each question and fill in the boxes with "B" if a biological hazard exists, "C" if a chemical hazard exists and "P" if a physical hazard exists.

List all incoming raw materials and ingredients by product name	Is a potential biological hazard associated with the item (e.g. bacteria, parasites)?	Is a potential chemical hazard associated with the item (e.g. antibiotic residues, pesticide residues, allergenic concerns)?	Is a potential physical hazard associated with the item? Address both metallic and non-metallic (e.g. environmental concerns – stones, dirt; foreign material – needles, bones)
Pork	B	C	P
Beef	B	C	P
Salt	B	C	P
Dextrose			
Water	B	C	
Spice	B		
Sodium nitrite			

C. Form #3: Flow Diagram

The flow diagram shows the relationship or processing link between each step. The process flow diagram should allow the entire manufacturing process to been seen at a glance. However, it should not be so detailed that the overall manufacturing process is lost or confused. This diagram will be used when conducting the hazard analysis for consideration of where hazards may occur in the manufacturing process.

Figure 7.5: HACCP Plan Form #3



Form #3: Flow Diagram | Plan Name:

PROCESS FLOW DIAGRAM SHOWING HOW THE PRODUCT MOVES THROUGH THE FACILITY

CONSTRUCT A FLOW DIAGRAM OF THE MANUFACTURING PROCESS.

Number each step in the process and identify if potential biological, chemical or physical hazards are associated with each step in the process.

Is a potential biological hazard associated with the step (e.g. bacterial contamination, bacteria on surfaces, bacterial growth)?

Is a potential chemical hazard associated with the step (e.g. sanitation residues, chemical contamination)?

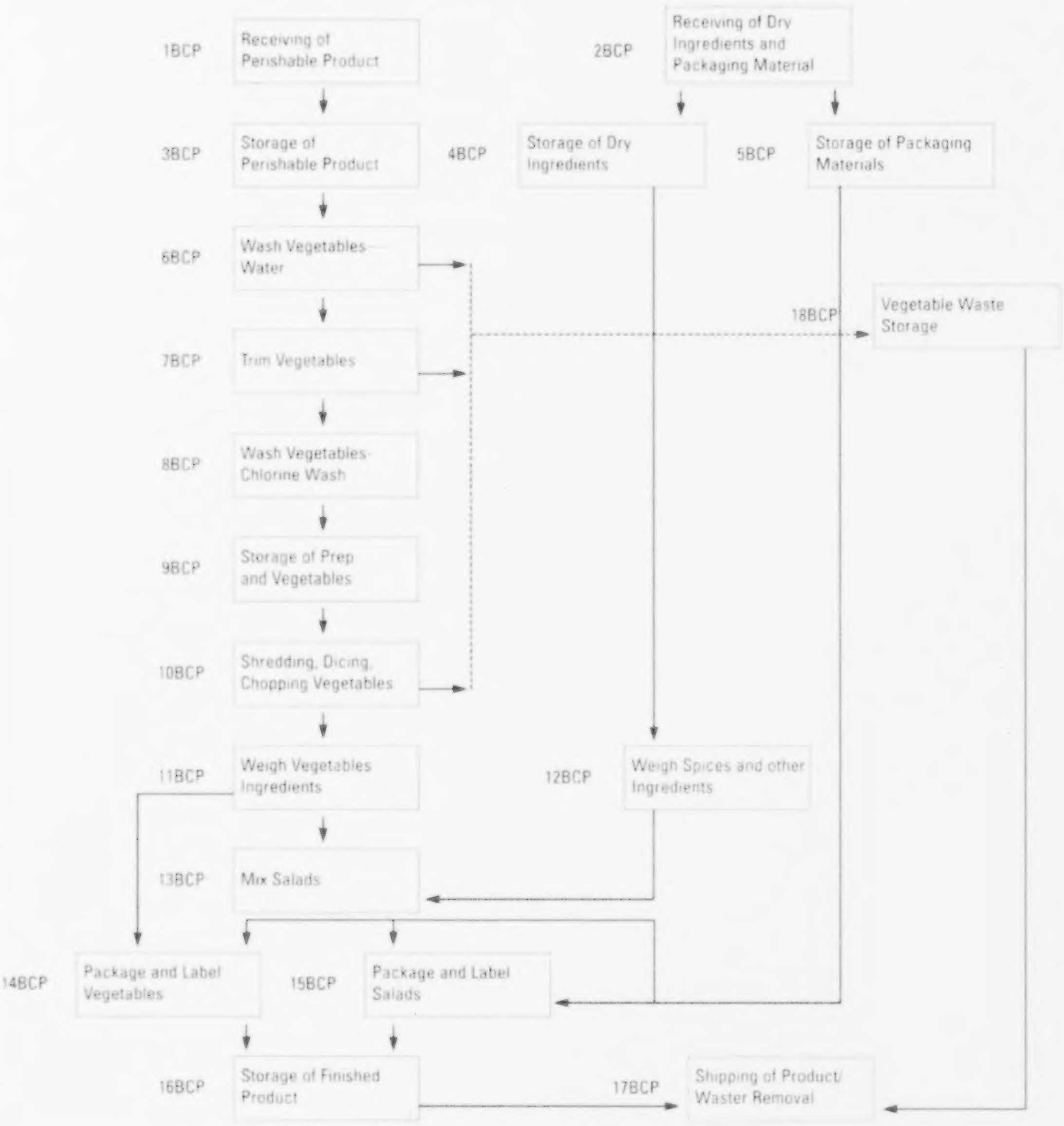
Is a potential physical hazard associated with the step (e.g. flaking paint, metal on metal contact)?

There is a blank form #3 provided in the *HACCP Advantage Program Manual*; however, it is advisable to draw your flow diagram on a separate page since there may not be enough room on the provided page. On this form you sequentially represent every process step used to manufacture your facility's product. The manufacturing flow should be illustrated with arrows between individual steps. Once the manufacturing steps are drawn, there are three questions to answer for each step shown:

1. Is a potential biological hazard (e.g., bacterial contamination, bacteria on surfaces, bacterial growth) associated with the step?
2. Is a potential chemical hazard (e.g., sanitation residues, chemical contamination) associated with the step?
3. Is a potential physical hazard (e.g., flaking paint, metal on metal contact) associated with the step?

Figure 7.6: HACCP Plan Form #3 Example

Form #3: Flow Diagram | Plan Name: Example


1BCP
Receiving of Perishable Product
2BCP
Receiving of Dry Ingredients and Packaging Material
3BCP
Storage of Perishable Product
4BCP
Storage of Dry Ingredients
5BCP
Storage of Packaging Materials
6BCP
Wash Vegetables—Water
18BCP
Vegetable Waste Storage
7BCP
Trim Vegetables
8BCP
Wash Vegetables-Chlorine Wash
9BCP
Storage of Prep and Vegetables
10BCP
Shredding, Dicing, Chopping Vegetables
11BCP
Weigh Vegetables Ingredients
12BCP
Weigh Spices and other Ingredients
13BCP
Mix Salads
14BCP
Package and Label Vegetables
15BCP
Package and Label Salads
16BCP
Storage of Finished Product
17BCP
Shipping of Product/ Waster Removal

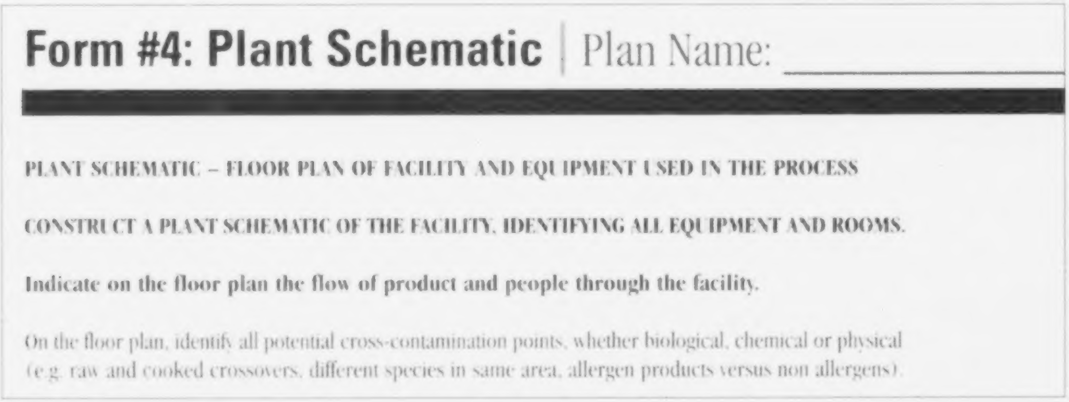
Identified hazards have to be represented on the flow diagram by the use of a B (biological), C (chemical) or P (physical) for the type(s) of hazard associated with each step. For example, for a Receiving step there are potential hazards such as:

- Biological hazards
  –product that has a growth of pathogens due to temperature abuse
  –products/ingredients accepted that do not meet the specifications
- Physical hazards
  –contamination due to damaged product containers.

D. Form #4: Plant Schematic

The plant schematic shows the relative amount of space allocated for each step outlined in the flow diagram and the flow of product and people through the facility. Once these flows are outlined on the schematic diagram, you can see potential sources of cross-contamination, overlap or backtracking. The plant schematic is also used in conducting the hazard analysis. To help when considering potential hazards, this diagram should allow for review of the physical aspects of the process in order to consider where hazards are likely to occur.

Figure 7.7: HACCP Plan Form #4



Form #4: Plant Schematic | Plan Name: ______________

PLANT SCHEMATIC – FLOOR PLAN OF FACILITY AND EQUIPMENT USED IN THE PROCESS

CONSTRUCT A PLANT SCHEMATIC OF THE FACILITY, IDENTIFYING ALL EQUIPMENT AND ROOMS.

Indicate on the floor plan the flow of product and people through the facility.

On the floor plan, identify all potential cross-contamination points, whether biological, chemical or physical (e.g. raw and cooked crossovers, different species in same area, allergen products versus non allergens).

There is a blank form #4 provided in the *HACCP Advantage Program Manual*; however, it is advisable to draw your own plant schematic on a separate page since there may not be enough room on the provided page. If your facility has blueprints, these may be used to complete this form.

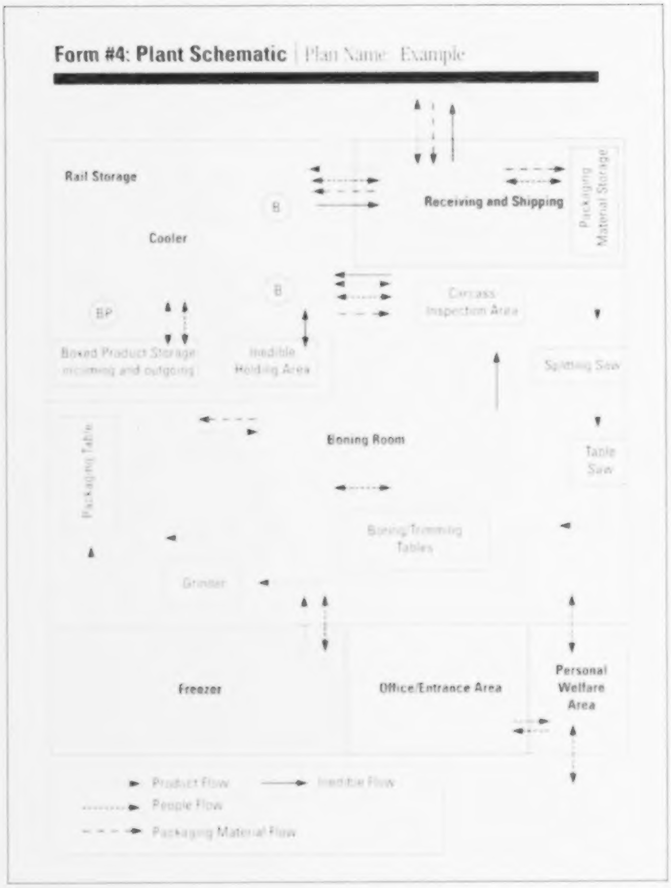
On this form, represent the physical manufacturing environment of the facility. The product and people flow should be illustrated with different arrows (e.g., colour, dash) between individual pieces of equipment or areas. Once the plant schematic is drawn, you should ensure that the following points are completed:

- All equipment and rooms are identified.
- Flow of product and people through the facility is identified.
- Potential cross-contamination points, whether biological, chemical or physical, are identified.

It is a good idea to show flcw of waste, raw vs. cooked, chemicals as well.
Hazards may be introduced through cross-contamination. This would be visible on the plant schematic where process and/or people flow arrows intersect. These potential cross-contamination hazards have to be represented on the plant schematic. Write a B (biological), C (chemical) or P (physical) for the type(s) of hazard associated with each step.

It is important to ensure that both the flow diagram and plant schematic are accurate and represent what is occurring in the facility, as they will be used in the hazard analysis. Therefore, it is important to verify the flow diagram (Form #3) and the plant schematic (Form #4) by physically walking through the facility during operation to ensure that all steps, people and product flows have been included, and all equipment is identified. You may find areas of potential cross-contamination during your verification of which you were not aware. Be sure to record all of these points on your flow diagram or plant schematic.

Figure 7.8: HACCP Plan Form #4 Example


Form #4: Plant Schematic | Plan Name: Example
Rail Storage
Cooler
B
Receiving and Shipping
Packaging Material Storage
B
Carcass Inspection Area
BP
Boxed Product Storage incoming and outgoing
Inedible Holding Area
Splitting Saw
Packaging Table
Boning Room
Table Saw
Boning/Trimming Tables
Grinder
Freezer
Office/Entrance Area
Personal Welfare Area
Product Flow
Inedible Flow
People Flow
Packaging Material Flow

E. Form #5: Hazard Analysis and Critical Control Point Determination

Form #5 is used to examine the hazards identified on Forms #2, #3 and #4 and to determine which hazards must be controlled at a CCP. In this section you will find a column-by-column explanation of how to complete Form #5.

In the *HACCP Advantage Program Manual* you will discover that Form #5 is actually three pages in length. The first page is for Incoming Materials, the second page is for Processing Steps and the third page is for the Plant Schematic. You may find that you need more than these three pages to include all of the hazards that you have identified on Forms #2, #3 and #4. If so, either make copies of the forms or create your own. Conducting a thorough hazard analysis is very important since any hazards not identified will not be addressed or controlled by the HACCP plan. Hazard analysis can also indicate where prerequisite programs may be lacking in controlling hazards. This step can be difficult but is crucial, especially if you have a complex manufacturing process, a large number of end products, or a large plant with many employees.

Figure 7.8: HACCP Plan Form #4 Example

Form #4: Plant Schematic
Rail Storage
Receiving and Shipping
Cooler
Brining Room
Freezer
Office/Entrance Area
Personnel Welfare Area

E. Form #5: Hazard Analysis and Critical Control Point Determination

Form #5 is used to examine the hazards identified on Forms #2, #3 and #4 and to determine which hazards must be controlled at a CCP. In this section you will find a column-by-column explanation of how to complete Form #5.

In the *HACCP Advantage Program Manual* you will discover that Form #5 is actually three pages in length. The first page is for Incoming Materials, the second page is for Processing Steps and the third page is for the Plant Schematic. You may find that you need more than these three pages to include all of the hazards that you have identified on Forms #2, #3 and #4. If so, either make copies of the forms or create your own. Conducting a thorough hazard analysis is very important since any hazards not identified will not be addressed or controlled by the HACCP plan. Hazard analysis can also indicate where prerequisite programs may be lacking in controlling hazards. This step can be difficult but is crucial, especially if you have a complex manufacturing process, a large number of end products, or a large plant with many employees.

technical**terms**

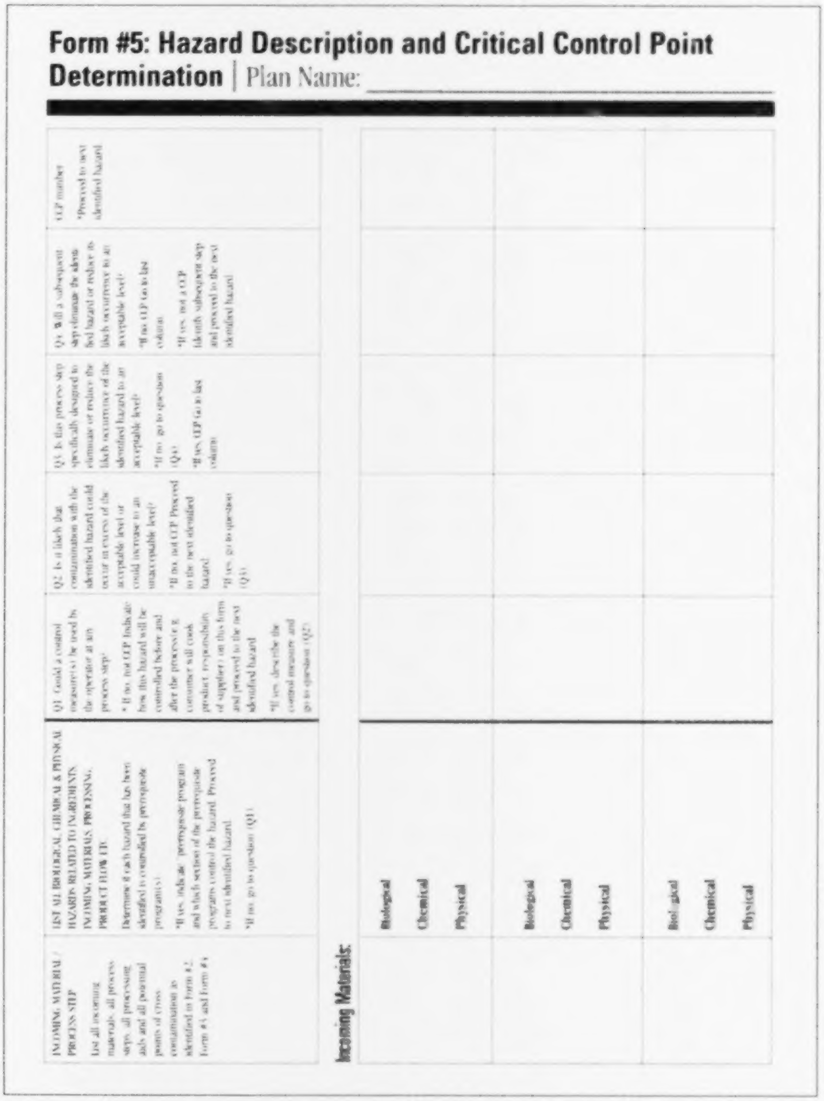
A **decision tree** is a reference tool that consists of a sequence of questions used to determine where CCPs are located.

Form #5 involves conducting a hazard analysis and incorporates the questions of a CCP decision tree.

i. Column One: Incoming Material/Process Step

In this column list all of the incoming materials, the process steps, processing aids and potential points of cross-contamination. This would include all ingredients and packaging materials that are used to manufacture the product. All of these items are identified in separate versions of Form #5 (i.e., Form 5—Incoming Materials, Form 5—Process Steps, Form 5—Plant Schematic). The information entered in this column is gathered from Forms #2, #3, and #4.

Figure 7.9: HACCP Plan Form #5



Form #5: Hazard Description and Critical Control Point Determination | Plan Name: ______________________

INCOMING MATERIAL / PROCESS STEP List all incoming materials, all process steps, all processing aids and all potential points of cross-contamination as identified in Form #2, Form #3 and Form #4	LIST ALL BIOLOGICAL, CHEMICAL & PHYSICAL HAZARDS RELATED TO INGREDIENTS, INCOMING MATERIALS, PROCESSING, PRODUCT FLOW ETC. Determine if each hazard that has been identified is controlled by prerequisite program(s). *If yes, indicate "prerequisite program" and which section of the prerequisite programs control the hazard. Proceed to next identified hazard. *If no, go to question (Q1).	Q1. Could a control measure(s) be used by the operator at any process step? * If no, not CCP. Indicate how this hazard will be controlled before and after the process(e.g. consumer will cook product, responsibility of supplier) on this form and proceed to the next identified hazard. *If yes, describe the control measure and go to question (Q2).	Q2. Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level? *If no, not CCP. Proceed to the next identified hazard. *If yes, go to question (Q3).	Q3. Is this process step specifically designed to eliminate or reduce the likely occurrence of the identified hazard to an acceptable level? *If no, go to question (Q4). *If yes, CCP. Go to last column.	Q4. Will a subsequent step eliminate the identified hazard or reduce its likely occurrence to an acceptable level? *If no, CCP. Go to last column. *If yes, not a CCP. Identify subsequent step and proceed to the next identified hazard.	CCP number *Proceed to next identified hazard.

Incoming Materials:

	Biological Chemical Physical					
	Biological Chemical Physical					
	Biological Chemical Physical					

For purposes of illustration, we will consider four separate examples. One incoming-material example, two processing-step examples and one plant-schematic example. Please note that these examples do not correlate to the examples used on the previous pages.

Example A—Incoming Material: Peanut Butter

In the first column you would simply write "peanut butter," possibly one of many identified ingredients originally recorded on Form #2.

Example B — Processing Step: Cooking

In the first column you would write "Step #18 Cooking." Again, this would come from Form #3, where the flow diagram would identify cooking as one processing step—#18 in this case.

Example C—Processing Step: Grinding

In the first column you would write "Step #8 Grinding" (another Form #3 processing step example).

Example D—Plant Schematic: Raw/Cooked Product Flow Intersection

In the first column you would write "Raw/cooked product flow intersection." This intersection point is a hazard that was identified on Form #4 Plant Schematic.

ii. Column Two: List All Hazards Related to Ingredients, Incoming Materials, Processing, Product Flow etc.

In this column list each biological, chemical and physical hazard associated with each item in column one. There may be one or more hazards associated with each item.

Here is where you identify the specific hazards that were listed as B, C, and P on Forms #2, #3, and #4.

For each identified hazard, column #2 requires you to answer "Yes" or "No" to *Determine if each hazard that has been identified is controlled by prerequisite program(s).* If a prerequisite program reduces, controls or eliminates the hazard, then there is no need to control it in your HACCP plan. If a prerequisite program does control the hazard, answer "Yes," identify the particular prerequisite program and move on to the next hazard. This is why the prerequisite programs are very important; they can reduce the number of CCPs that you have in your HACCP plan.

Example A—Incoming Material: Peanut Butter

In column two, the following identified hazards would be written for each of the three types of hazards:

Biological

- none

Chemical

- peanut allergen

Q. Is this hazard controlled by a prerequisite program?

A. "Yes: O2.6 Allergen Control"

Physical

- none

The hazard identified with this particular ingredient is controlled by prerequisite programs; therefore, there is no need to continue further on Form #5 with this particular hazard.

Example B—Processing Step: Cooking

In column two the following identified hazards would be written:

Biological

- "Contamination from condensate"

  Q. Is this hazard controlled by a prerequisite program?

  A. "Yes: E3.1 Internal Structures and Fittings"

- "Pathogen survival due to improper temperature distribution"

  Q. Is this hazard controlled by a prerequisite program?

  A. "Yes: E4.1 Equipment Design, Construction and Installation"

- "Pathogen survival due to improper equipment calibration"

  Q. Is this hazard controlled by a prerequisite program?

  A. "Yes: O4.1 Preventive Maintenance and Calibration Monitoring"

- "Survival of pathogen due to improper cooking"

  Q. Is this hazard controlled by a prerequisite program?

  A. "No: The prerequisite programs do not control this hazard."

Chemical

- "Chemical contamination due to residual cleaners/sanitizers on containers/equipment"

  Q. Is this hazard controlled by a prerequisite program?

  A. "Yes: P3.1 Sanitation Program, O3.1 Cleaning and Sanitizing"

Physical

- None

All of the hazards associated with cooking were controlled through the prerequisite programs except one—"Survival of pathogens due to improper cooking." This hazard would continue to be followed through Form #5.

Example C—Processing Step: Grinding

In column two the following hazards would be written:

Biological

- "Contamination with pathogens due to improper employee handling"

  Q. Is this hazard controlled by a prerequisite program?

  A. "Yes: P1.1 Good Manufacturing Practices Program, T1.1 Good Manufacturing Practices Training"

Chemical

- "Chemical contamination due to residual cleaners/sanitizers on containers/equipment"

  Q. Is this hazard controlled by a prerequisite program?

  A. "Yes: P3.1 Sanitation Program, O3.1 Cleaning and Sanitizing"

Physical

- "Contamination with metal filing from metal on metal contact"

  Q. Is this hazard controlled by a prerequisite program?

  A. "No: The prerequisite programs do not control this hazard."

Again here, we have a hazard that needs to be followed through Form #5; this time a physical hazard (metal filings) has been identified.

Example D—Plant Schematic: Raw/Cooked Product Flow Intersection

In column two the following hazard would be written:

Biological

- "Cross-contamination of cooked product with pathogens from raw product"

  Q. Is this hazard controlled by a prerequisite program?

  A. "Yes: E2.1 Cross-Contamination Control, O1.7 Access and Traffic Patterns"

This hazard identified on the plant schematic is controlled by prerequisite programs; therefore, there is no need to continue further with Form #5 for this particular hazard.

iii. Column Three: Q1, Question One

Column three asks a yes/no question regarding the uncontrolled hazard identified in column two and, based on the results, gives you direction on how to proceed. The question:

> *Could a control measure(s) be used by the operator at any process step?*

In this column you must determine if there are any control measures that can be used at any processing steps to control the hazard. It is possible that you may have to adapt your process to include an appropriate control measure not currently in use. Some hazards cannot be controlled at the facility and will remain without implemented control measures; however, this situation should be avoided if possible. If you answer "no" to this question, the decision tree provides the following direction:

> *If no, not a CCP, indicate how this hazard will be controlled before and/or after the process (e.g., consumer will cook product responsibility of supplier) on this form and proceed to the next identified hazard.*

Uncontrolled hazards will be listed separately on Form 7 (see explanation below). You must state who does have control over these hazards. This may be done at the farm, by another processor or even by the end consumers themselves (as is the case with the cooking of raw meat). In this case write "See Form 7" in column Three.

If you answer "Yes" to this question and can identify a control measure that could be used to control the hazard, the decision tree provides the following direction:

> *If yes, describe the control measure and go to next question (Q2).*

We will illustrate this process using examples B and C. Remember that the hazard in examples A were controlled by prerequisite programs, and thus the rest of the columns in Form #5 do not need to be completed.

Example B—Processing Step: Cooking

Biological

- Survival of pathogens due to improper cooking

  Q1. Could a control measure be used by the operator at any process step?

  A. "Yes. A control measure to ensure that the product is cooked to an adequate internal temperature could be used."

Example C—Processing Step: Grinding

Physical

- Contamination with metal filing from metal-on-metal contact

  Q1. Could a control measure be used by the operator at any process step?

  A. "Yes: A metal detector would detect and remove all product that contained metal filings of a certain size."

For the purposes of Example C we will assume that the processing line includes a metal detector at packaging. This will be important later in Form #5.

iv. Column Four: Q2, Question Two

This column asks the next yes/no question. It asks:

> *Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level?*

This question deals with the possibility of the hazard being present in excess of an acceptable level or increasing to an unacceptable level. This will allow you to rule out any hazards that exist but are so unlikely to occur that it doesn't make sense to have any controls for them. If the hazard is unlikely to occur at an unacceptable level, the decision tree provides the following direction:

> *If no, not a CCP, proceed to the next identified hazard.*

This means that we have completed the decision tree for this particular hazard and can continue to the next hazard.

If, however, the hazard is likely to occur at an unacceptable level the following guidance is provided:

> *If yes, go to next question (Q3).*

Using our examples, this question would be completed as follows:

Example B—Processing Step: Cooking

Biological

- Survival of pathogen due to improper cooking

  Q2. Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level?

  A. "Yes." If the product is not fully cooked, the hazard could occur at an unacceptable level.

Example C—Processing Step: Grinding

Physical

- Contamination with metal filing from metal-on-metal contact.

  Q2. Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level?

  A. "Yes." Metal filings could occur of significant size.

v. Column Five: Q3, Question Three

This question asks you to consider the ability of this specific processing step to control the hazard. It enquires:

> *Is this process step specifically designed to eliminate or reduce the likely occurrence of the identified hazard to an acceptable level?*

This question is used to determine whether or not the particular processing step is specifically designed to eliminate or reduce the occurrence of the hazard to an acceptable level. In the case of the Form #5 for Incoming Materials and Form #5 for the Plant schematic, this question is not applicable since it applies only to process steps. Therefore, you would record "not applicable" and proceed to the next column.

If the step is not designed to control or eliminate the hazard, move to the next column:

> *If no, go to next question (Q4)*

However, if the processing step is designed to eliminate or reduce the hazard to an acceptable level, this processing step is a CCP.

> *If yes, this is a CCP. Go to the last column.*

If this step results in a CCP, you can skip column six and proceed directly to the last column where CCPs are identified.

Example B—Processing Step: Cooking

Biological

- Survival of pathogen due to improper cooking

  Q3. Is this process step specifically designed to eliminate or reduce the likely occurrence of the hazard to an acceptable level?

  A. "Yes." The process step of cooking is designed to eliminate the pathogenic bacteria that are associated with the product.

Since we answered "Yes" to this question, this means that cooking is a CCP. Move to the last column.

Example C—Processing Step: Grinding

Physical

- Contamination with metal filing from metal-on-metal contact

  Q3. Is this process step specifically designed to eliminate or reduce the likely occurrence of the hazard to an acceptable level?

  A. "No." The grinding process step is not designed to remove metal filings from the product.

Remember that when answering this question you are assessing the particular processing step the hazard is associated with (in this case, grinding). It is important to not apply this question with any process steps identified as a control measure in column three (Q1)
(in this case, metal detection).

vi. Column Six: Q4, Question Four

Column six asks the last question in the CCP decision tree. It asks:

> *Will a subsequent step eliminate the identified hazard or reduce its likely occurrence to an acceptable level?*

In other words, is there a processing step further down the process flow where this hazard can be controlled? If not, then this particular processing step is a CCP:

> *If no, this is a CCP. Go to the last column.*

If yes, record this later processing step in this column; the current processing step being assessed is not a CCP.

If yes, this is not a CCP. Identify the subsequent step and proceed to the next identified hazard.

CCPs do not necessarily have to be located where the hazard occurs and commonly do not. They may be located at a subsequent step where the hazard can be controlled more easily or with greater efficiency.

Example C—Processing Step: Grinding

Physical

- Contamination with metal filing from metal-on-metal contact

  Q4. Will a subsequent step eliminate the identified hazard or reduce its likely occurrence to an acceptable level?

  A. "Yes. The metal detector on the packaging line will eliminate the hazard and remove all product that contains metal filings of a certain size."

This hazard can be detected and controlled with a metal detector further down the process. Therefore, you need to identify this subsequent step (metal detector on the packaging line in the example) and the current processing step being assessed, grinding in the example, is not a CCP. To identify the subsequent step you should reference the step number from the process flow (#28 Metal detection, for the purpose of this example). Later when you examine the metal detector step itself with the decision tree it will become a CCP.

vii. Column Seven: CCP Number

Under this column record the CCP Number. The numbering system should be as follows: record the CCP numerically and whether it is biological (B), chemical(C) or physical (P). So, if it's the first CCP controlling a biological hazard you would record "1B."

Of our four examples, only example B generated a CCP to be numbered.

Example B—Processing Step: Cooking

Biological

- Survival of pathogen due to improper cooking.

  "CCP 1B"

Examples A through D are illustrated on the next pages in the completed Form #5s.

Figure 7.10: HACCP Plan Form #5 Example

Form #5: Hazard Description and Critical Control Point Determination | Plan Name: Example

PROCESS STEP / INCOMING MATERIAL List all incoming materials, all process steps, all processing aids and all potential points of cross-contamination as identified in Form # 2, Form # 3 and Form # 4.	LIST ALL BIOLOGICAL, CHEMICAL & PHYSICAL HAZARDS RELATED TO INGREDIENTS, INCOMING MATERIALS, PROCESSING, PRODUCT FLOW ETC. Determine if each hazard that has been identified is fully controlled by prerequisite program(s). *If yes – indicate "prerequisite program" and which section of the prerequisite programs control the hazard and proceed to next identified hazard. *If no – proceed to question 1(Q1)	Q1. Could a control measure(s) be used by the operator at any process step? *If no – not CCP. Indicate how this hazard will be controlled before and after the process (i.e., consumer cook product, responsibility of supplier) on this form and proceed in the next identified hazard. *If yes – describe the control measure and go to question 2 (Q2).	Q2. Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level? *If no – not CCP. Proceed to the next identified hazard. *If yes – next question (Q3).	Q3. Is this process step specifically designed to eliminate/reduce the likely occurrence of the identified hazard to an acceptable level? *If no – go to next question (Q4). *If yes – CCP. Go to last column.	Q4 Will a subsequent step eliminate the identified hazard or reduce its likely occurrence to an acceptable level? *If no – CCP. Go to last column. *If yes – not a CCP. Identify subsequent step and proceed to the next identified hazard.	CCP number *Proceed to next identified hazard.
INCOMING MATERIALS:						
EXAMPLE A Peanut Butter	**Chemical:** Peanut allergen Yes: O2.6 Allergen Control					
PROCESS STEPS:						
EXAMPLE B Step # 18 Cooking	**Biological:** Contamination from condensate. Yes: E3.1 Internal Structures and Fittings Pathogen survival due to improper temperature distribution. Yes: E4.1 Equipment Design, Construction and Installation Pathogen survival due to improper equipment calibration. Yes: O4.1 Preventive Maintenance and Calibration Monitoring Survival of pathogens due to improper cooking. No: The prerequisite programs do not control this hazard. **Chemical:** Chemical contamination due to residual cleaners/sanitizers on containers/equipment. Yes: P3.1 Sanitation Program, O3.1 Cleaning and Sanitizing	Yes. Cooking to an adequate internal temperature.	Yes	Yes		CCP 1B

Figure 7.11: HACCP Plan Form #5 Example

Form #5: Hazard Description and Critical Control Point Determination | Plan Name: Example

PROCESS STEP / INCOMING MATERIAL List all incoming materials, all process steps, all processing aids and all potential points of cross-contamination as identified in Form # 2, Form # 3 and Form # 4.	LIST ALL BIOLOGICAL, CHEMICAL & PHYSICAL HAZARDS RELATED TO INGREDIENTS, INCOMING MATERIALS, PROCESSING, PRODUCT FLOW ETC. Determine if each hazard that has been identified is fully controlled by prerequisite program(s). *If yes – indicate "prerequisite program" and which section of the prerequisite programs control the hazard and proceed to next identified hazard. *If no – proceed to question 1(Q1)	Q1. Could a control measure(s) be used by the operator at any process step? *If no – not CCP. Indicate how this hazard will be controlled before and after the process (i.e., consumer cook product, responsibility of supplier) on this form and proceed in the next identified hazard. *If yes – describe the control measure and go to question 2 (Q2).	Q2. Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level? *If no – not CCP. Proceed to the next identified hazard. *If yes – next question (Q3).	Q3. Is this process step specifically designed to eliminate/reduce the likely occurrence of the identified hazard to an acceptable level? *If no – go to next question (Q4). *If yes – CCP. Go to last column.	Q4 Will a subsequent step eliminate the identified hazard or reduce its likely occurrence to an acceptable level? *If no – CCP. Go to last column. *If yes – not a CCP. Identify subsequent step and proceed to the next identified hazard.	CCP number *Proceed to next identified hazard.
PROCESS STEPS:						
EXAMPLE C Step #18 Grinding	**Biological**: Contamination with pathogens due to improper employee handling. Yes: P1.1 Good Manufacturing Practices Program, T1.1 Good Manufacturing Practices Training					
	Chemical: Chemical contamination due to residual cleaners/ sanitizers on containers/equipment. Yes: P3.1 Sanitation Program, O3.1 Cleaning and Sanitizing					
	Physical: Contamination with metal filing from metal-on-metal contact. No: The prerequisite programs do not control this hazard.	Yes. Metal Detection	Yes	No	Yes. The metal detector on the packaging line will eliminate the hazard.	

Figure 7.12: HACCP Plan Form #5 Example

Form #5: Hazard Description and Critical Control Point Determination | Plan Name: Example

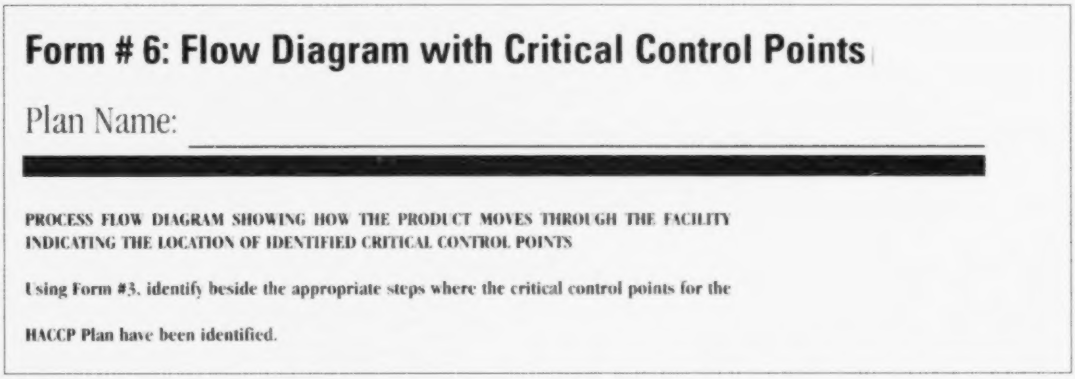
PROCESS STEP / INCOMING MATERIAL List all incoming materials, all process steps, all processing aids and all potential points of cross-contamination as identified in Form # 2, Form # 3 and Form # 4.	LIST ALL BIOLOGICAL, CHEMICAL & PHYSICAL HAZARDS RELATED TO INGREDIENTS, INCOMING MATERIALS, PROCESSING, PRODUCT FLOW ETC. Determine if each hazard that has been identified is fully controlled by prerequisite program(s). *If yes – indicate "prerequisite program" and which section of the prerequisite programs control the hazard and proceed to next identified hazard. *If no – proceed to question 1(Q1)	Q1. Could a control measure(s) be used by the operator at any process step? *If no – not CCP. Indicate how this hazard will be controlled before and after the process (i.e., consumer cook product, responsibility of supplier) on this form and proceed in the next identified hazard. *If yes – describe the control measure and go to question 2 (Q2).	Q2. Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level? *If no – not CCP. Proceed to the next identified hazard. *If yes – next question (Q3).	Q3. Is this process step specifically designed to eliminate/reduce the likely occurrence of the identified hazard to an acceptable level? *If no – go to next question (Q4). *If yes – CCP. Go to last column.	Q4 Will a subsequent step eliminate the identified hazard or reduce its likely occurrence to an acceptable level? *If no – CCP. Go to last column. *If yes – not a CCP. Identify subsequent step and proceed to the next identified hazard.	CCP number *Proceed to next identified hazard.
PLANT SCHEMATIC DIAGRAM:						
EXAMPLE D Raw/Cooked Product Flow Intersection	**Biological:** Cross-contamination of cooked product with pathogens from raw product. Yes: E2.1 Cross-Contamination Control, O1.7 Access and Traffic Patterns					

F. Form #6: Flow Diagram with Critical Control Points

Form #6 shows not only the same flow diagram that was developed on Form #3, but also the location of the CCPs that are determined through Form #5.

Copy the information from Form #3 onto Form #6 and then wherever you have found a CCP on Form #5 record this CCP at the appropriate processing step.

Figure 7.13: HACCP Plan Form #6



Form # 6: Flow Diagram with Critical Control Points

Plan Name: ____________________

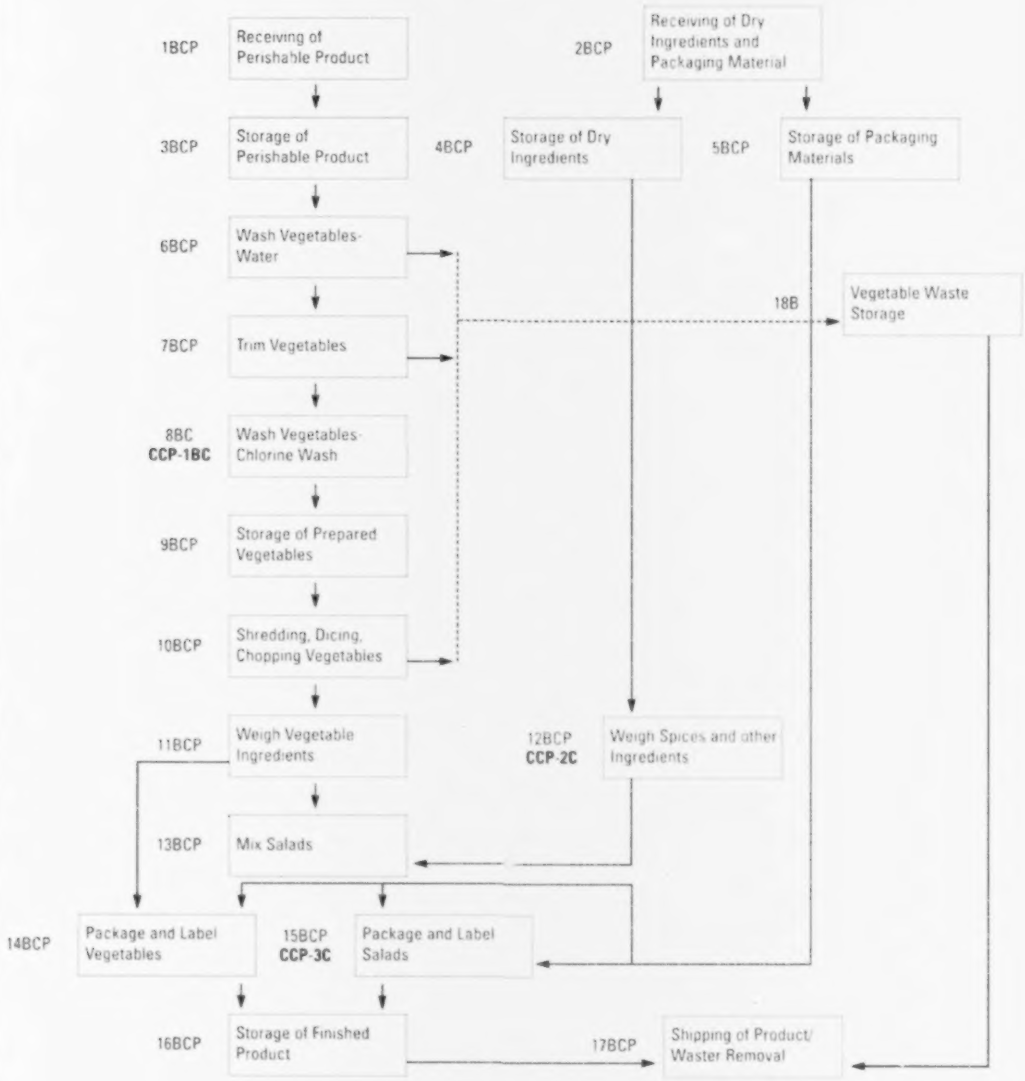
PROCESS FLOW DIAGRAM SHOWING HOW THE PRODUCT MOVES THROUGH THE FACILITY INDICATING THE LOCATION OF IDENTIFIED CRITICAL CONTROL POINTS

Using Form #3, identify beside the appropriate steps where the critical control points for the HACCP Plan have been identified.

Figure 7.14: HACCP Plan Form #6 Example

Form # 6: Flow Diagram with Critical Control Points

Plan Name: Example


1BCP
Receiving of Perishable Product
2BCP
Receiving of Dry Ingredients and Packaging Material
3BCP
Storage of Perishable Product
4BCP
Storage of Dry Ingredients
5BCP
Storage of Packaging Materials
6BCP
Wash Vegetables-Water
18B
Vegetable Waste Storage
7BCP
Trim Vegetables
8BC
CCP-1BC
Wash Vegetables-Chlorine Wash
9BCP
Storage of Prepared Vegetables
10BCP
Shredding, Dicing, Chopping Vegetables
11BCP
Weigh Vegetable Ingredients
12BCP
CCP-2C
Weigh Spices and other Ingredients
13BCP
Mix Salads
14BCP
Package and Label Vegetables
15BCP
CCP-3C
Package and Label Salads
16BCP
Storage of Finished Product
17BCP
Shipping of Product/ Waster Removal

G. Form #7: Uncontrolled Hazards

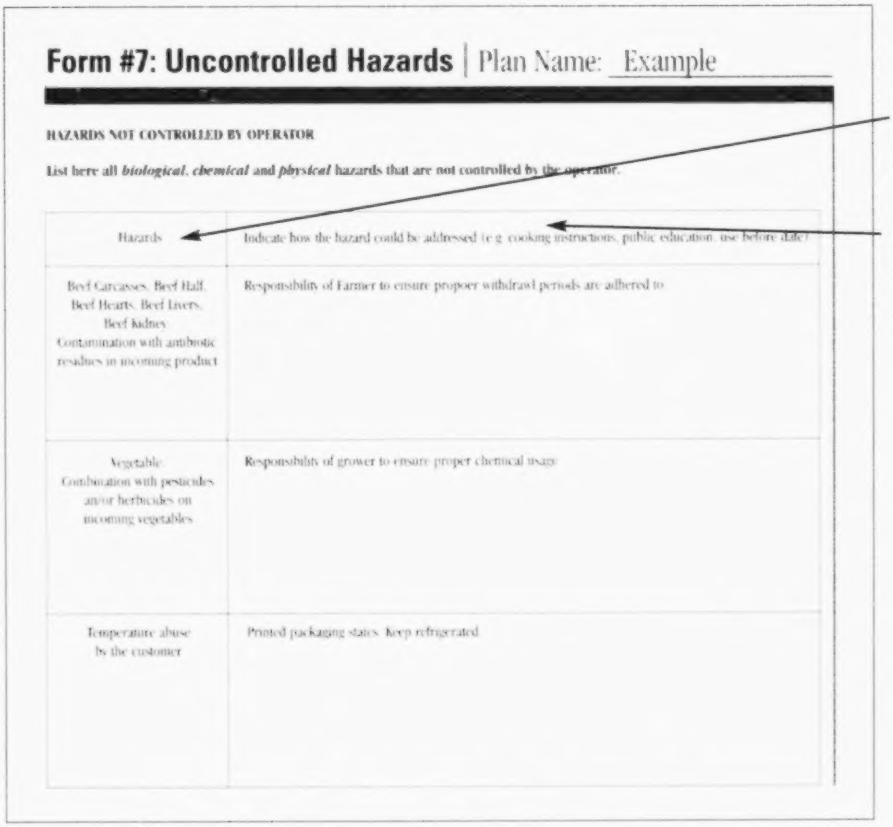
Form #7 is used to record any hazards that cannot be controlled through your own prerequisite programs and HACCP plan.

In the first column record the hazard. In the second column record how the hazard may be controlled elsewhere in the food chain. Any hazards listed on Form #5, but not controlled by a prerequisite program or a CCP must be listed on this form. Any hazard that results in a "No" in column three (Q1) of Form #5 must be entered here.

Figure 7.15: HACCP Plan Form #7

Form #7: Uncontrolled Hazards | Plan Name

Figure 7.16: HACCP Plan Form #7 Example



Form #7: Uncontrolled Hazards | Plan Name: Example

HAZARDS NOT CONTROLLED BY OPERATOR

List here all *biological, chemical* and *physical* hazards that are not controlled by the operator.

Hazards	Indicate how the hazard could be addressed (e.g. cooking instructions, public education, use before date)
Beef Carcasses, Beef Half, Beef Hearts, Beef Livers, Beef Kidney Contamination with antibiotic residues in incoming product	Responsibility of Farmer to ensure propoer withdrawl periods are adhered to
Vegetable Combination with pesticides an/or herbicides on incoming vegetables	Responsibility of grower to ensure proper chemical usage
Temperature abuse by the customer	Printed packaging states: Keep refrigerated

Record any hazards for which you do not have control

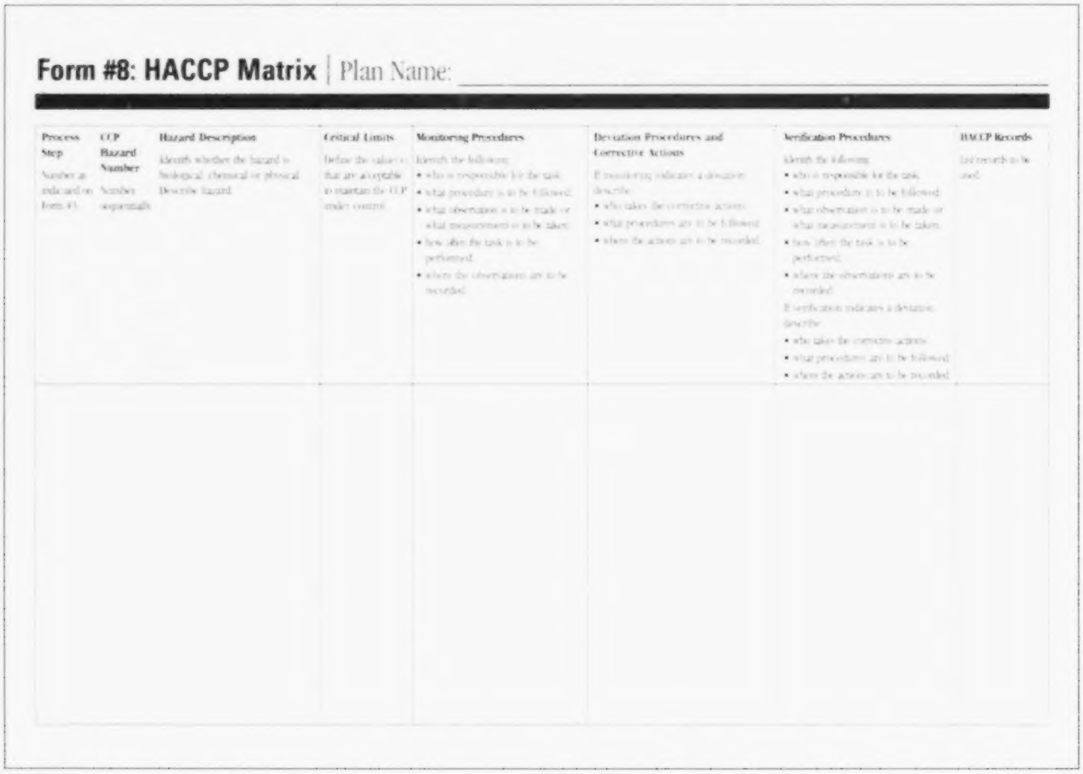
Record how the hazard may be controlled

H. Form #8: HACCP Matrix

Form #8 is the HACCP Matrix. The purpose of this form is to determine and record the following information for each CCP:

- The process step at which the CCP is located
- The CCP number
- A description of the hazard controlled by the CCP
- The critical limits for the CCP
- The monitoring procedures for the CCP
- The corrective actions for the CCP
- The verification procedures for the CCP
- The HACCP record(s) used to record information pertaining to the CCP.

Figure 7.17: HACCP Plan Form #8



Form #8: HACCP Matrix | Plan Name: ____________________

Process Step	CCP Hazard Number	Hazard Description	Critical Limits	Monitoring Procedures	Deviation Procedures and Corrective Actions	Verification Procedures	HACCP Records
Number as indicated on Form #3.	Number sequentially.	Identify whether the hazard is biological, chemical or physical. Describe hazard.	Define the values that are acceptable to maintain the CCP under control.	Identify the following: • who is responsible for the task • what procedure is to be followed • what observation is to be made or what measurement is to be taken • how often the task is to be performed • where the observations are to be recorded	If monitoring indicates a deviation, describe: • who takes the corrective actions • what procedures are to be followed • where the actions are to be recorded	Identify the following: • who is responsible for the task • what procedure is to be followed • what observation is to be made or what measurement is to be taken • how often the task is to be performed • where the observations are to be recorded If verification indicates a deviation, describe: • who takes the corrective actions • what procedures are to be followed • where the actions are to be recorded	List records to be used.

Below is a column-by-column description of the HACCP Matrix

i. Column One: Process Step

Enter the processing step at which the CCP identified on Form #5 is located.

For example purposes, we will consider the cooking processing step CCP identified in the Form #5 example (Example B under *Column One: Incoming Material/Process Step*). This was Step #18 Cooking; therefore, that is what you would enter in the column:

- "Step #18 Cooking"

ii. Column Two: CCP Hazard Number

The CCP number is entered directly from Form #5. The CCP number is identified in the last column of Form #5.

In the example, the cooking CCP on Form #5 was CCP 1B, therefore, this is what you would write in this column.

- "CCP 1B"

iii. Column Three: Hazard Description

In this column identify whether the hazard is biological, chemical or physical, and describe the hazard that the CCP is meant to control. These hazard descriptions can be copied from the hazards listed in column two of Form #5.

In our cooking example the hazard is:

- "Biological—Survival of pathogens due to improper cooking"

iv. Column Four: Critical Limits

Column four is where you record the limits necessary to produce a safe product. Critical limits:

- Are criteria that separate safe product from unsafe product
- Define maximum and/or minimum values to which a parameter must be controlled at a CCP
- Mark the boundary where a food safety hazard can definitively be prevented, eliminated, or reduced to an acceptable level
- Must be clearly defined, objective and measurable
- Are often determined from sources such as regulatory guidelines and published scientific data.

Continuing with the cooking example, a ready-to-eat product must be cooked to ensure effective destruction of all pathogens. In our example, the product must be cooked to an internal temperature of 69°C or 156°F to effectively kill all harmful bacterial. In column four you would write:

- "Product must be cooked to a minimum temperature of 69°C or 156°F"

v. Column Five: Monitoring Procedures

Monitoring is the process of conducting a planned sequence of observations or measurements to determine if a CCP is under control. For each CCP, monitoring procedures must be documented and implemented to ensure that the critical limits identified in the previous column are being met. Monitoring of each CCP is performed at planned frequencies and the results are recorded.

Each monitoring procedure must outline:

- **Who** will perform the monitoring activity (remember that this individual must be trained; see prerequisite program T8.1)
- **What** will be monitored (e.g., smokehouse temperature, water temperature, metal detector, can seal strength)
- **How** it will be monitored (including the exact procedure to be followed), where the procedure should take place and proper use of any instruments
- **How** often or the frequency it will be monitored
- **Where** the monitoring results are recorded.

The monitoring procedures you develop should be reliable and reproducible. The instruments you choose should be precise (measure to the detail required) and accurate (measure correctly each time). Ideally, monitoring procedures would be performed continuously (i.e., all product is monitored against the critical limit). However, in reality it is not always feasible or practical to monitor a CCP on a continuous basis. The frequency of monitoring procedures must be balanced with practicality. This frequency must be achievable while at the same time realistic enough that if a deviation (failure to meet the critical limit) occurs, it is possible to regain control of all affected product. Keep in mind that if critical limits are not met, all product since the last acceptable monitoring results may be affected and therefore must be controlled.

Monitoring procedures can also indicate if there is a trend toward loss of control. Even if critical limits are being met, the results from monitoring activities can provide early warning signs that the process may eventually be out of control. This provides the opportunity to make adjustments to the process prior to failure of the system.

Using the cooking example (we'll say it's cooked roast beef), the monitoring procedure may look something like this:

- "The oven operator shall monitor the cooking CCP by measuring the internal temperature of the largest piece of meat exiting the oven with a calibrated thermometer every 15 minutes. The internal temperature must be greater then 69°C or 156°F. If the critical limit is not met, initiate corrective actions. Record all findings on the cook production record."

vi. Column Six: Deviation Procedures and Corrective Actions

HACCP plan corrective actions are predetermined activities that are initiated when CCP monitoring indicates that a deviation has occurred. For each CCP there must be planned, written corrective actions. You will need to describe ahead of time what you will do when monitoring indicates that the critical limit is not achieved.

The objectives of taking corrective actions are threefold, and therefore written corrective actions must achieve these three goals:

- Regain control of the hazard
- Control all affected product and determine the disposition of affected product
- Correct the root cause of the problem to prevent a reoccurrence of the deviation.

It is important to stress that corrective actions must identify, locate and control any food product that was produced while the CCP was out of control. Appropriate product dispositions may include detaining, properly reworking if possible, or destroying.

The concept of asking *Why* five times to determine the root cause of the problem (discussed in Chapter 6) also applies here.

Any corrective actions taken must always be recorded. This is commonly done on the same record on which the monitoring is recorded. The cause for the deviation, if known, should also be recorded.

Using the cooked roast beef example, if monitoring indicates that the minimum internal temperature of 69°C or 156°F was not reached, the following corrective action procedures would be initiated:

"If the minimum cook temperature *(69°C or 156°F) has not been reached, the cook(s) will:*

- Hold all the roast beef that was cooked in the oven since the last acceptable monitoring results (15 minutes ago)
- Re-cook product until the desired temperature has been reached
- Inform the management team if the oven cannot achieve the target temperature to re-cook the product."

"The management team will:

- Investigate cause of oven failure
- Repair or replace malfunctioning items and make appropriate adjustments to prevent a re-occurrence
- Re-cook all product placed on hold as a result of the initial deviation when oven has been repaired or discard all held product."

"All parties will:

- Record all corrective actions on the Cook Production Record CCP 1B including date, time and initials."

vii. Column Seven: Verification Procedures

Verification procedures are the application of methods, procedures, tests and other evaluations to determine conformance with the HACCP plan. Verification activities are performed to ensure that the HACCP plan is being properly followed and that the appropriate records are being completed. Like monitoring procedures, verification procedures are performed at a predetermined frequency; however, they are performed less frequently than monitoring procedures. Commonly, verification is referred to as "monitoring the monitor" or more simply ensuring that what the monitor is doing is correct and that all issues are properly handled.

Using our roast beef example, a sample verification procedure would be:

- "Daily, the HACCP coordinator will review all monitoring records to confirm that the critical limits were met and recorded.
- Once per month, the HACCP coordinator will perform an on-site assessment to confirm that the monitoring procedure is being performed as written.
- On a quarterly basis, cooked roast beef samples will be subjected to laboratory analysis to confirm hazard control.
- All verification activities are record on the Production Verification Record with date and verifier initials."

viii. Column Eight: HACCP Records

Many records will be generated once your HACCP system is in place. Records are the "proof" you rely on in an audit or potential food safety crisis. They show that your system was functioning effectively and that identified hazards were properly controlled. In column eight of the HACCP matrix you reference all records that could be used in monitoring that specific CCP. This includes monitoring records, corrective action records, verification records and any other records pertinent to the CCP.

Using our cooked roast beef example, column eight might be filled out in the following manner:

- "Cook Production Record CCP 1B"

Figure 7.16 is an example of a completed HACCP matrix. This should provide some added insight on how to complete this important form.

Figure 7.18: HACCP Plan Form #8 Example

Form #8: HACCP Matrix | Plan Name: Example

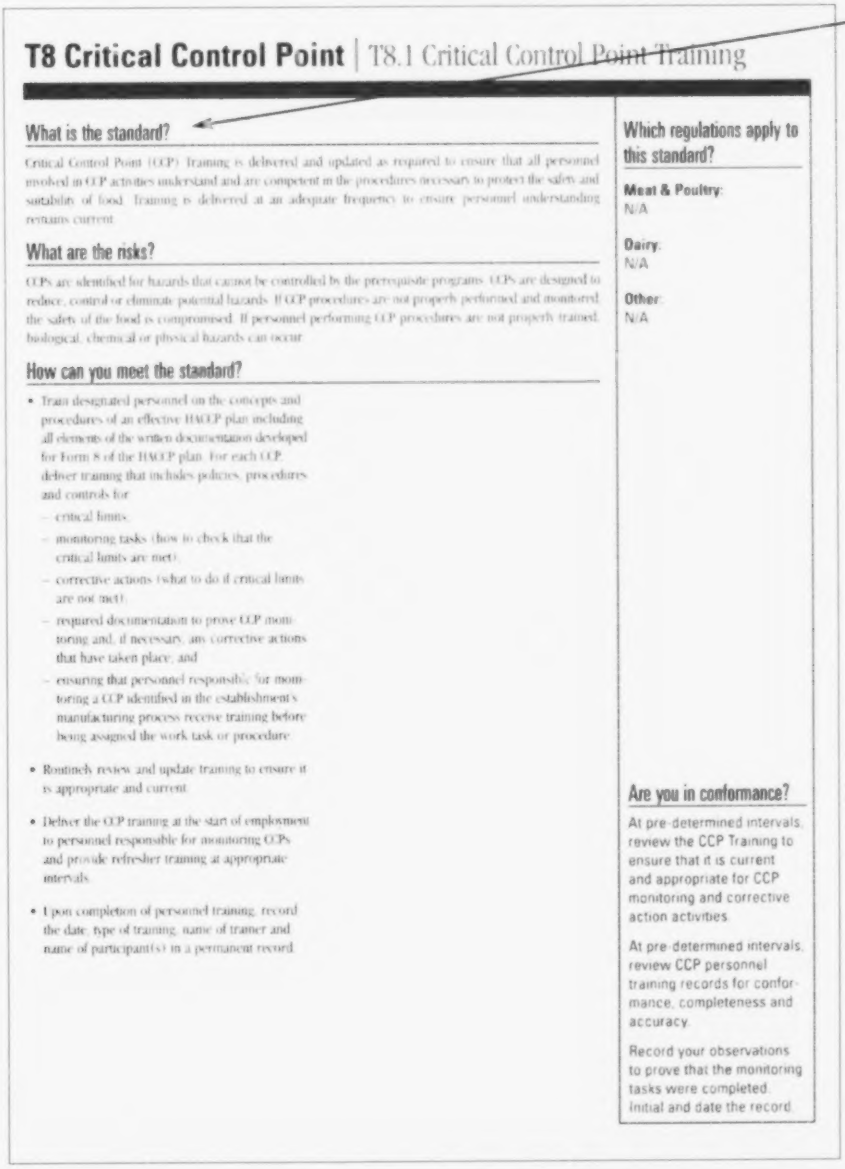
Process Step Number as indicated on Form #3.	**CCP Hazard Number** Number sequentially.	**Hazard Description** Identify whether the hazard is biological, chemical or physical. Describe hazard.	**Critical Limits** Define the value(s) that are acceptable to maintain the CCP under control.	**Monitoring Procedures** Identify the following: • who is responsible for the task; • what procedure is to be followed; • what observation is to be made or what measurement is to be taken; • how often the task is to be performed; • where the observations are to be recorded.	**Deviation Procedures and Corrective Actions** If monitoring indicates a deviation, describe: • who takes the corrective actions; • what procedures are to be followed; • where the actions are to be recorded.	**Verification Procedures** Identify the following: • who is responsible for the task; • what procedure is to be followed; • what observation is to be made or what measurement is to be taken; • how often the task is to be performed; • where the observations are to be recorded. If verification indicates a deviation, describe: • who takes the corrective actions; • what procedures are to be followed; • where the actions are to be recorded.	**HACCP Records** List records to be used.
Step 18 Cooking	CCP 1B	Biological — Survival of pathogens due to improper cooking.	Product must be cooked to a minimum internal temperature of 69°C/156°F	The cook will test the internal temperature of the largest piece of meat exiting the oven with a calibrated thermometer every 15 minutes to ensure that the critical limit has been reached. If the critical limits have not been reached, the cook will initiate corrective actions. Results will be recorded on the Cook Production record including date, time and initials.	If the minimum cook temperature (69°C) has not been reached, the cook(s) will: • Hold all the roast beef that was cooked since the last good check. Re-cook product until the desired temperature has been reached. • Inform management if the oven cannot achieve the target temperature. • The management team will: • Investigate cause of oven failure. • Repair or replace malfunctioning items and make adjustments to prevent a re-occurrence. • Re-cook all product placed on hold as a result of the initial deviation when oven has been repaired or discard all held product. • All parties will: • Record all corrective actions on the "Cook Production Record CCP1B" including date, time and initials.	• Daily, the HACCP coordinator will review all monitoring records to confirm that the critical limits were met and recorded. • Once per month, the HACCP coordinator will perform an on-site assessment to confirm that the monitoring procedure is being performed as written. • On a quarterly basis, cooked roast beef samples will be subjected to laboratory analysis to confirm hazard control. • All verification activities are recorded on the Production Verification Record with date, time and verifier initials.	Cook Production Record CCP 1B

4. TRAINING YOUR EMPLOYEES FOR CCPS

Prerequisite programs were explained in Chapter 2. One of the groups of prerequisite programs is for training. You can have complete prerequisite programs and HACCP plans on paper, but if you don't have trained employees monitoring them your HACCP system is destined to fail.

Let's focus on T8.1 Critical Control Point Training. This prerequisite program cannot be implemented until you have a written HACCP plan.

Figure 7.19: CCP Training Prerequisite Program Explanation



T8 Critical Control Point | T8.1 Critical Control Point Training

What is the standard?

Critical Control Point (CCP) Training is delivered and updated as required to ensure that all personnel involved in CCP activities understand and are competent in the procedures necessary to protect the safety and suitability of food. Training is delivered at an adequate frequency to ensure personnel understanding remains current.

What are the risks?

CCPs are identified for hazards that cannot be controlled by the prerequisite programs. CCPs are designed to reduce, control or eliminate potential hazards. If CCP procedures are not properly performed and monitored the safety of the food is compromised. If personnel performing CCP procedures are not properly trained, biological, chemical or physical hazards can occur.

How can you meet the standard?

- Train designated personnel on the concepts and procedures of an effective HACCP plan including all elements of the written documentation developed for Form 8 of the HACCP plan. For each CCP, deliver training that includes policies, procedures and controls for:
    - critical limits;
    - monitoring tasks (how to check that the critical limits are met);
    - corrective actions (what to do if critical limits are not met);
    - required documentation to prove CCP monitoring and, if necessary, any corrective actions that have taken place; and
    - ensuring that personnel responsible for monitoring a CCP identified in the establishment's manufacturing process receive training before being assigned the work task or procedure.
- Routinely review and update training to ensure it is appropriate and current.
- Deliver the CCP training at the start of employment to personnel responsible for monitoring CCPs and provide refresher training at appropriate intervals.
- Upon completion of personnel training, record the date, type of training, name of trainer and name of participant(s) in a permanent record.

Which regulations apply to this standard?

Meat & Poultry:
N/A

Dairy:
N/A

Other:
N/A

Are you in conformance?

At pre-determined intervals, review the CCP Training to ensure that it is current and appropriate for CCP monitoring and corrective action activities.

At pre-determined intervals, review CCP personnel training records for conformance, completeness and accuracy.

Record your observations to prove that the monitoring tasks were completed. Initial and date the record.

Critical Control Point (CCP) Training is delivered and updated as required to ensure that all personnel involved in CCP activities understand and are competent in the procedures necessary to protect the safety and suitability of food. Training is delivered at an adequate frequency to ensure personnel understanding remains current.

This standard must be implemented effectively in order to have an effective HACCP plan. Remember these elements when considering CCP training:

- Ensure employees understand the reason for HACCP.
- Ensure employees understand the reason for monitoring the CCP.
- Clearly identify the critical limits and ensure employees understand them.
- Clearly identify the monitoring procedures and ensure employees understand them.
- Ensure employees know what corrective actions to take if there is a deviation.
- Ensure employees are aware of the record-keeping requirements.

One simple way to remind your employees of the critical limits or any other CCP parameter is to include these on the record. For example:

Figure 7.20: CCP Monitoring Record Example

CCP COOK RECORD

Critical Limits: The internal temperature of the product must reach 69 °C or 156 °F in the core of the product.

DATE	PRODUCT NAME	SMOKEHOUSE NUMBER/ KETTLE	INTERNAL TEMPERATURE	INITIALS
May 10	Meatloaf	6	69.5°C	*HK*

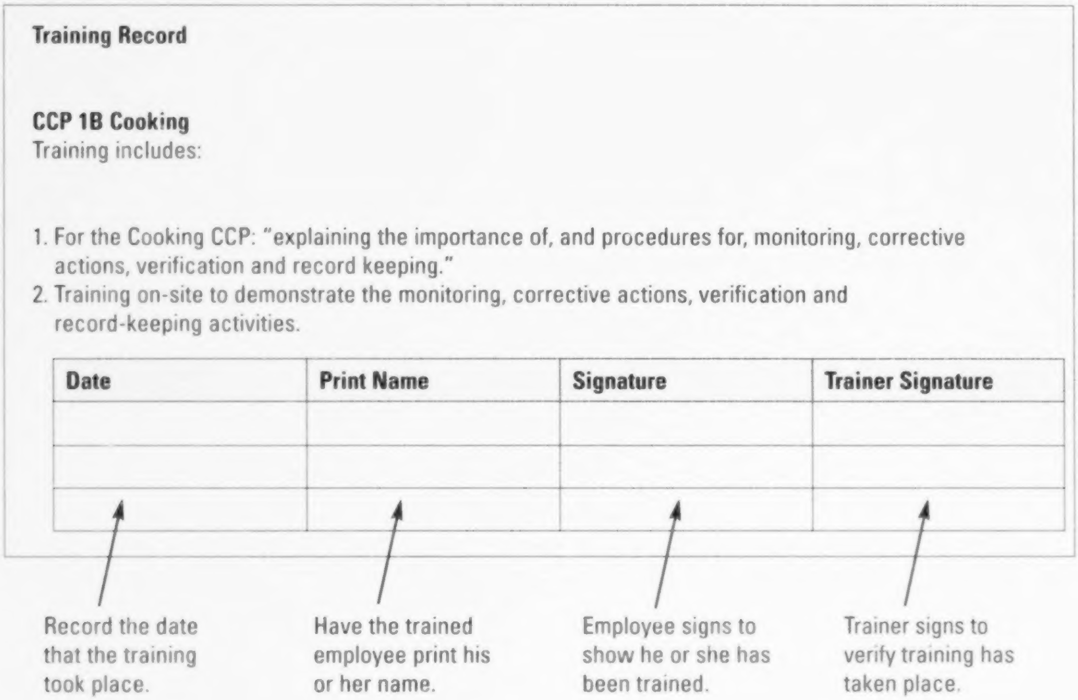
To train employees on CCPs take the people responsible for monitoring and verification of each CCP to the location where monitoring and verification is performed. Using the HACCP matrix (Form #8), demonstrate each step of the monitoring and verification procedures. Don't forget to provide training on corrective actions and record keeping. Commonly, the HACCP coordinator is responsible for this training.

You should also train backup employees since holidays and sick days must be taken into account. When you have finished the training, have employees sign and date a training record to indicate they have been trained for the CCP and understand what they are required to do.

During initial CCP training you may find that you need to fine-tune your monitoring procedures or corrective actions; perhaps there is a better employee to do the verification. It is a good idea to get input from the people doing the monitoring and verification; they may have some ideas on how to make a form easier to complete or other good suggestions on how things may be made more efficient and feasible. The people doing the work are a great resource. Use their input.

You may experience resistance from some of your employees when implementing the HACCP plans. This is another good reason to get their involvement when developing the monitoring procedures; people are usually more supportive of a process in which they have had input.

Figure 7.21: CCP Training Record Example



Training Record

CCP 1B Cooking
Training includes:

1. For the Cooking CCP: "explaining the importance of, and procedures for, monitoring, corrective actions, verification and record keeping."
2. Training on-site to demonstrate the monitoring, corrective actions, verification and record-keeping activities.

Date	Print Name	Signature	Trainer Signature

Record the date that the training took place.

Have the trained employee print his or her name.

Employee signs to show he or she has been trained.

Trainer signs to verify training has taken place.

IN SUMMARY

After reading this chapter, you should be able to provide answers to the following questions:

1. What are the HACCP plans meant to control?
2. What are the eight HACCP plan forms?
3. How do I complete the HACCP plan forms?
4. Where do I find hazards associated with my products and processes?
5. How do I determine CCPs?
6. How do I monitor and verify CCPs?
7. Why is training employees so important?

Points to remember

- HACCP plans control the product and the processes in your facility.
- The HACCP decision tree will help you determine your CCPs.
- Once you have determined your CCPs, you must continually monitor and verify them at the stated frequency in your HACCP plan.
- Ensure that only trained employees are monitoring and verifying your CCPs.

CHAPTER**EIGHT**

Maintaining Your HACCP System

Key Points in Chapter 8

HACCP systems require continual maintenance.

HACCP system maintenance involves ongoing monitoring, verification, corrective actions, validation, internal audits, system updates and ongoing training.

A HACCP system can be improved by reassessing how procedures such as monitoring are conducted and who conducts them.

Maintaining Your HACCP System

1. MAINTENANCE OF YOUR HACCP SYSTEM

Once your HACCP system is developed and implemented, your work is not over; you must continually maintain your HACCP system to ensure that it is current and remains effective in controlling food safety hazards. Improper or infrequent HACCP system maintenance can lead to HACCP system failure and may result in decertification. The person responsible for HACCP in the facility (i.e., the HACCP coordinator) has the authority to make changes to your HACCP system.

technical**terms**

A **logbook** is a book in which the dates and nature of all changes regarding the *HACCP Advantage* system are recorded. It is recommended that you use a book from which the pages cannot be removed.

All changes to your HACCP system must be recorded. Most often, companies will record changes in a logbook, which provides an ongoing history of your HACCP system.

During the certification process, the auditors will check your logbook to see if you have made any changes to your HACCP system since your last audit.

Table 8.1: Example of a Logbook Entry

Date	**Prerequisite Program/ HACCP Plan**	**Change Made**	**Initial**
May 4, 2004	05.1 Pest Control Monitoring	Increased the monitoring of the outside bait stations to once every two weeks from once per month due to increase number of pest sightings.	*HK*

Note: This change would have to be reflected in the written Pest Control program and in any records that are used to record pest control monitoring and corrective actions.

2. WHAT DOES HACCP SYSTEM MAINTENANCE INVOLVE?

HACCP system maintenance involves:

- Ongoing monitoring, verification and corrective action tasks for the life span of the HACCP system
- Validation activities
- Planned internal audits of the prerequisite programs and HACCP plans at a predetermined frequency to ensure that all programs are being properly followed and documented
- Follow-up and closing of open corrective actions from previous audits
- Updating your HACCP system when changes to your facility or processing operation are made
- Updating your HACCP system in light of new scientific information
- Updating your HACCP system in response to new regulations
- Ongoing training to ensure that all personnel involved with the system remain properly trained.

A. Ongoing Monitoring, Verification and Corrective Actions

Monitoring, verification and corrective action tasks that are written in the prerequisite programs and/or HACCP plans must be performed for the life span of the HACCP system. The associated record keeping must also be continually performed.

Ongoing monitoring and verification can provide information that leads you to make changes to your system. For example, you may find that you need to increase a monitoring frequency if numerous deviations are being discovered. Or you may need to decrease the frequency of monitoring activities to be more realistic and manageable for the person responsible.

Through monitoring procedures you may be able to detect a trend toward loss of control. The results from monitoring activities can provide early warning signs that a process may eventually be out of control. This provides the opportunity to make adjustments to the process prior to failure of the system.

The development of both prerequisite programs and HACCP plans requires that you determine corrective actions to be taken if deviations occur (see Chapters 6 and 7). And, as discussed, corrective actions must include measures to determine the root cause of the problem in order to correct the problem. The changes that result from these actions may constitute a change in your HACCP system and must be recorded in your logbook.

B. Validation Activities

Validation activities should be conducted yearly at minimum. You should consider the following questions to ensure your HACCP system is effective (i.e., valid):

- Does the HACCP system identify all significant food safety hazards?
- Does the HACCP system control identified food safety hazards (based on, for example, scientific evidence, regulatory requirements, internationally accepted standards or expert determination)?
- Does the HACCP system result in the desired outcomes?
- Does the HACCP system meet all the requirements of the *HACCP Advantage?*

You may find problems with your HACCP system as you go through this process. This is not necessarily a bad thing; better to find and solve problems before the auditors find them. If you identify any problems, you may need to make changes to your HACCP system to correct them.

technical**terms**

Verification activities confirm that the HACCP plan(s) is functioning as intended and as written.

Validation activities confirm that the HACCP system includes all significant food safety hazards and is effective in controlling these hazards.

C. Internal Audits

At minimum you should conduct an internal audit of the prerequisite programs and HACCP plans each year. It is not necessary to complete all internal audit activities at the same time; these can be spread out over the entire year. To schedule these internal audit activities, develop a calendar that outlines when different auditing tasks must be performed. Internal audits, as well as external audits, may highlight deviations that require corrective actions. Refer to Chapter 9 for more information regarding internal audits.

D. Corrective Actions from Previous Audits

During HACCP certification audits, the auditors may identify non-conformances in your HACCP system that require corrective actions. When this is the case, you must respond to the auditors with a Corrective Action Plan (CAP) to address the non-conformance. This action plan may include changes to the HACCP system. It is important to ensure that all such corrective actions are performed within the allotted timeframe. Refer to Chapter 9 for more information regarding HACCP certification audits.

E. Changes to Your Facility or Processes

Your HACCP system must be updated when changes to your facility or processing operation are made, including when:

- New ingredients, products, or product types are introduced
- New product lines are introduced
- A product line is discontinued
- New equipment is installed
- New chemicals or processes are being used.

In addition, your HACCP team list must be kept up-to-date, reflecting employee leaves, changes, or new hires.

F. New Scientific Information

If new scientific information or evidence becomes available that impacts your HACCP system, your system will likely need to be updated and documentation of this scientific information kept on record. This includes information regarding:

- New or emerging pathogens
- Hazards not previously known to be associated with a product or process
- New critical limit parameters to effectively control a hazard
- New control-measure techniques.

G. New Regulations

As part of your Food Safety Management System (FSMS), discussed in Chapter 4, you must continually be aware of any new food safety regulations that impact you. Any new regulations, or changes in regulations, that impact your operation must be reflected in your system.

H. Ongoing Training

HACCP-related training must be performed on an ongoing basis. For example, as stated in the prerequisite programs (T1.1), training must be delivered to all new employees at the start of employment, and refresher training must be provided at appropriate intervals.

3. IMPROVING YOUR HACCP SYSTEM

Generally speaking, people strive for continual improvement. The same goes for the HACCP system that you have implemented in your facility. You have decided to strengthen the safety of the food you manufacture by implementing the *HACCP Advantage*, and by keeping your HACCP system up-to-date and reassessing it frequently, you will find many ways to improve your system. Here are some areas to look at to improve your HACCP system:

- Make monitoring easier. For example, the record that is used to record your information may be changed to make it more user friendly or streamlined.
- Ensure that you have the best person possible performing your monitoring and/or verification processes.
- File all records where you know you can find them quickly.
- Keep track of corrective actions. You may find trends that suggest improvements to your HACCP system.
- Benefit from outside audits and make changes to your HACCP system accordingly.
- Make sure that you have backup HACCP team members/monitors/coordinators trained for holidays and sick days.

IN **SUMMARY**

After reading this chapter, you should be able to provide answers to the following questions:

1. What is a logbook and why is it necessary?
2. What do I need to do to maintain my HACCP system over time?
3. When will I need to make changes to my HACCP system?

Points to remember

- Keep your prerequisite programs and HACCP plans up-to-date.
- Record any changes to your HACCP system in your logbook.
- The auditors will look for your logbook and the changes made to your HACCP system.

CHAPTER NINE

Certification and Recognition of Your *HACCP Advantage* System

Key Points in Chapter 9

Before you apply for certification, you should ensure that your HACCP system is working effectively. An internal audit is a good method to determine this.

Audits for certification involve assessment of your written programs as well as examination of those written programs in process.

Certification is an ongoing process: Your HACCP system must be maintained on an ongoing basis and must pass yearly audits to retain your certification.

Certification can be revoked, or denied, if your HACCP system is ineffective or incomplete or if you fail to address non-conformances within the set time frame.

CHAPTER **NINE**

Certification and Recognition of Your *HACCP Advantage* System

1. INTRODUCTION

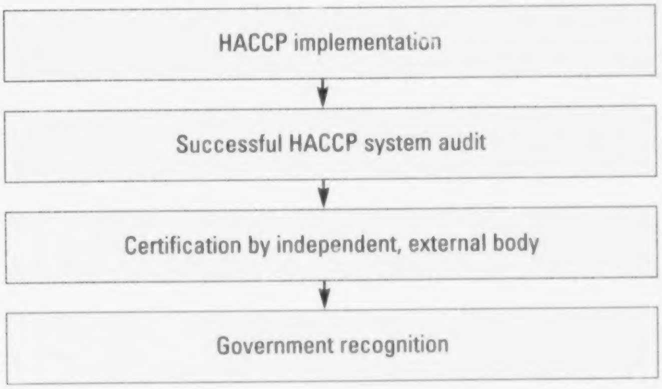
Before applying for certification you should understand the roles various parties play in certification and your responsibilities for maintaining certification. To help ensure certification of your HACCP system, there are a few important steps you can take.

A. A Short Lesson in Terminology

For many, one goal of HACCP implementation, beyond food safety, is acceptance of their HACCP system by customers, thereby improving marketability. Acceptance usually requires review by an independent external body. Such review can include terms such as "recognition" or "certification"; however, each of these words has a different meaning[1].

In general, governments provide HACCP recognition, while independent, external bodies provide certification. These certification bodies audit individual HACCP systems to verify that they meet standard requirements. Successful audits lead to certification. Certification leads to recognition.

Figure 9.1: Flow diagram of auditing, certification and recognition


HACCP implementation
Successful HACCP system audit
Certification by independent, external body
Government recognition

technical**terms**

Recognition is a formal government acknowledgment and approval of an implemented HACCP system.

Certification is the issuing of a written assurance (e.g., certificate) by an independent, external body that has audited a HACCP system and verified that it conforms to the requirements specified in the standard.

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[1] International Organization for Standardization. "Certification, registration and accreditation." Retrieved June 2004 from www.iso.org.

B. Why Apply for Certification, and Why Are Audits Necessary?

Certification is an important part of any HACCP program. Objective, independent certification provides regulators, stakeholders and, most importantly, customers with evidence that food products are produced under an effective food safety (in this case, HACCP) system. Certification by a recognized body verifies that an implemented HACCP system conforms to a standard, is complete, and is effectively designed and maintained. The recognition that comes with certification can produce increased employee motivation and ownership of food safety, as well as improved consumer confidence.

Audits are necessary to determine if certification should be granted. During an audit your HACCP system is examined and assessed. Objective evidence is gathered to demonstrate that your HACCP system is properly implemented and working effectively. Audits also promote continual improvement in your food safety systems, thereby ensuring that you are supplying your customers with safe food.

C. Roles and Responsibilities

There are three main parties involved in HACCP recognition:
- The government
- The certification body
- You, the operator.

i. Responsibilities of Government—Ontario Minisrty of Agriculture and Food (OMAF)

In this regard, the key responsibilities of government are defining the standards and recognizing certified systems. OMAF has defined the *HACCP Advantage* standards in the *HACCP Advantage Program Manual*; OMAF has designated and recognized the Canadian General Standards Board (CGSB) as the certification body for the *HACCP Advantage*; and OMAF recognizes *HACCP Advantage* systems certified by CGSB.

ii. Responsibilities of Certification Bodies

Certification bodies are responsible for auditing the HACCP system to ensure that it:

- Meets the standards
- Is implemented as written
- Is effective in controlling food safety hazards.

Certification bodies provide written assurances of successful certification (usually in the form of a certificate) to the operators. In the case of the *HACCP Advantage*, CGSB will audit HACCP systems with respect to the standards defined in the *HACCP Advantage Program Manual*. Certification bodies also conduct annual audits for ongoing certification.

iii. Responsibilities of Applicants/Operators

You, as the applicant and food processing operator, are responsible for developing and implementing an effective HACCP system specific to your facility. You must then maintain your system by:

- Monitoring each prerequisite program
- Monitoring and verifying each CCP
- Keeping accurate records
- Taking appropriate corrective actions when deviations are identified
- Updating your system as needed.

Management is ultimately responsible for the effectiveness and accuracy of the HACCP system and its documentation.

Operators also have responsibilities during the certification process. If any non-conformances are found during auditing, it is your responsibility to effectively address these in a set time frame. You must also inform the certification body of any changes or updates to your HACCP system before the start of any subsequent audits.

2. PREPARING FOR A CERTIFICATION AUDIT

Preparation is key to an efficient and successful audit. Organization and thoroughness are reflections of professionalism and a HACCP system that is in control.

Before you apply for certification you should ensure that your operations and personnel are ready for auditing. There are some key steps you can take, such as an internal audit, to help ensure your success.

You are ready to apply for certification after your HACCP system has been fully implemented and you are certain that it is functioning effectively. It is advisable that you allow your HACCP system to function for three to four months after implementation before applying for certification.

A. Internal Audit

i. What, Who and When?

An internal audit is a self-evaluation of your HACCP system. Using a critical eye, your HACCP system is thoroughly examined. It is commonplace for the HACCP coordinator to conduct the internal audit. The best time to conduct your first internal audit is a few months after your HACCP system is implemented and prior to certification application. This allows some time for your HACCP system to start functioning as it normally would. It would be prudent to develop a regular schedule of internal audits to ensure that your system continues to operate effectively.

ii. How to Conduct an Internal Audit

To conduct an internal audit you should develop a method for assessing your HACCP system. Useful aids include worksheets or checklists. Your checklists should be tailored to your specific facility and HACCP system. As you develop your internal audit, refer to the *HACCP Advantage Program Manual* for the requirements; you may even want to make reference in your worksheets/checklist to specific standards.

To assist you in developing and conducting your own internal audit, sample checklists have been provided at the end of this chapter. You should adapt these suggestions to work for your facility.

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Why invest the time and effort in an internal audit?

- Identification of deficiencies
- Determination of root causes of deficiencies
- Correction of deficiencies prior to external audits
- Preparation for external audits
- Possibly fewer external auditing hours
- Probably improved external auditing results
- Continual improvement opportunities
- Reinforcement of food safety awareness.

There are three general stages you should include in your internal audit:

1. Check that your documentation is complete and there are no missing components.
2. Check that your written programs meet the requirements and will produce the required outcomes.
3. Check that your written programs are actually being implemented as written and that personnel are sufficiently trained and competent. For example:

- Are the prerequisite programs followed as written?
  - Are monitoring procedures followed?
  - Are correction actions taken when required?
  - Are results recorded?

- Are the HACCP plan(s) followed as written?
  - Are CCPs monitored?
  - Are correction actions taken when critical limits are not met?
  - Are verification procedures performed?
  - Are results recorded?

As you conduct your internal audit, if you find any items that are missing, incomplete or ineffective, note these non-conformances. Following your audit you will need to:

- Develop CAPs to fix the non-conformances.
- Carry out these plans.
- Check that your correction actions were effective.

If, during your internal audit, you identify areas that need further work, now is the time to fully address these areas. *You should not proceed with application for certification until you are certain you have addressed all non-conformances identified in your internal audit.* Proceeding before you are ready may lead to significant corrective actions to address before you can be certified or worse, a failed audit. Not being prepared will likely cost you more time, effort and money.

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Internal Audit Follow-Up

One of the most important parts of an internal audit is your follow-up; a common pitfall following an internal audit is inaction. Simply recording a deficiency is not enough; the root cause of a non-conformance must be determined. Non-conformances must also be corrected or addressed. You must then verify that the measures taken were completed and effective.

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It is important that management review the results of your internal audit. It is management's responsibility to ensure that the HACCP system is operating sufficiently before proceeding with the application for certification.

After you have conducted a few internal audits take the opportunity to examine your checklists for repeated non-conformances and determine how you could change your HACCP system to prevent them in the future. Such preventative measures can improve your auditing results and may lead to efficiencies in your HACCP system.

B. Preparing for a Certification Audit

Here are six other helpful hints to aid you in your preparation for audits.

i. Personnel Preparation

As part of your HACCP system all personnel with HACCP responsibilities should be trained and able to answer interview questions regarding:

- Their roles and specific duties
- The importance of their roles
- Where to find information (e.g., manuals, supporting materials) regarding their roles
- The records they are responsible for.

Training should emphasize the consequences of personnel not completing their duties as required.

ii. Confirmation of Outsourcing Effectiveness

It is your responsibility to ensure that outsourced programs (e.g., pest control or sanitation) are effective, meet the standards and are properly documented.

iii. Organized Documentation

The better organized your documentation, the better your HACCP system will be and the smoother your audits will proceed. Have all documentation stored in designated areas and organized in a manner that is easy to follow. You should also make sure that there are no inconsistencies in your documentation (e.g., HACCP plan forms, records).

iv. Designated Area

It is recommended that you have a designated area for auditors to sit and examine your documents; for example, a boardroom, a meeting room, an office or a quiet corner with sufficient workspace.

v. Management Involvement

Management should demonstrate commitment to the HACCP system by taking the time to meet the auditors and join the opening and closing meetings. This is also important for better management understanding, especially if corrective actions require their decisions and financial support.

vi. GMP and Safety Adherence

You should treat the auditors like any other visitors; they must follow your policies and procedures for GMPs and safety procedures. Be sure to explain these to the auditors at your opening meeting and be prepared to provide them with any necessary apparel (e.g., boots, hairnets, coats/smocks).

3. STEPS FOR *HACCP ADVANTAGE* CERTIFICATION

Once you have implemented your HACCP system, monitored it for a sufficient time period and successfully completed your internal audit, you are ready to apply to CGSB for certification.

Only *HACCP Advantage* systems certified by CGSB will be recognized by OMAF. CGSB will administer the delivery of certification services for the *HACCP Advantage* and will use the services of qualified food safety auditors to perform the audits of individual *HACCP Advantage* systems. CGSB will provide details of the costs for certification and ongoing auditing. The types of fees you may expect include an application fee, an annual listing fee and hourly auditor fees. The certification process documented below is accurate at the time of publication of this guidebook.

Upon your request for application, CGSB will send you an application package. Once you have completed and submitted the application package, CGSB will begin the certification process and schedule the on-site audits.

CGSB auditors will conduct audits in three general phases:

1. Documentation Review

The documentation review is conducted to ensure that no major components of your HACCP system are missing. You will need to provide enough of your written programs to demonstrate that you have fully implemented your HACCP system.

2. On-Site Systems Audit

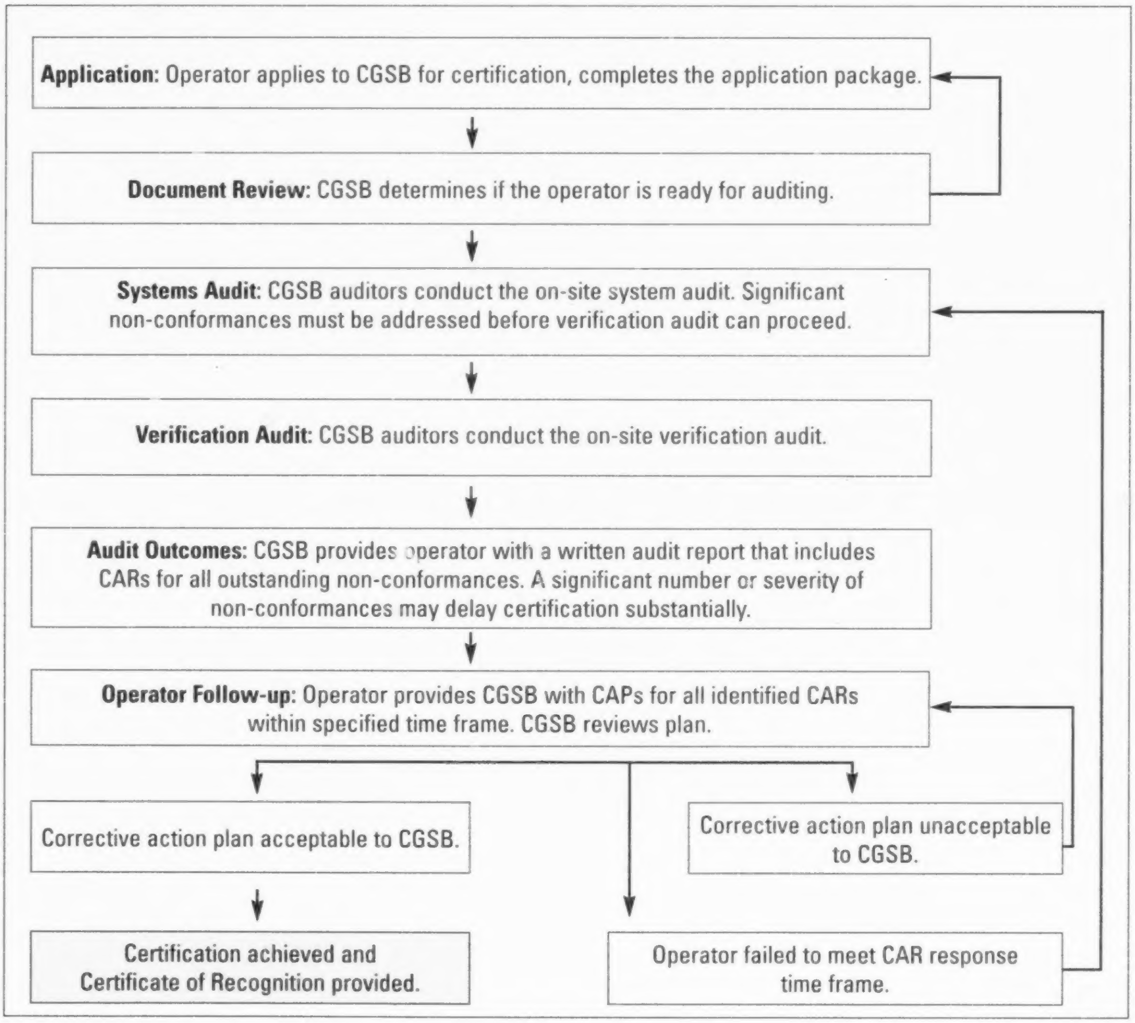
The systems audit is essentially a “desk audit” conducted to confirm that you have effectively addressed all the prerequisite program standards and that your HACCP plan(s) are complete and effective (the auditors check what you say you are going to do).

3. On-Site Verification Audit

The on-site verification ensures that your written prerequisites programs and HACCP plan(s) are performed as written (the auditors check that you are doing what you said you would do).

CGSB auditors will identify to you any elements of your HACCP system that are lacking. To obtain certification you are required to sufficiently address these Corrective Action Requests (CARs) in the set time frame.

Figure 9.2: Flow Diagram of Steps to Achieve HACCP Advantage Certification



Application: Operator applies to CGSB for certification, completes the application package.

Document Review: CGSB determines if the operator is ready for auditing.

Systems Audit: CGSB auditors conduct the on-site system audit. Significant non-conformances must be addressed before verification audit can proceed.

Verification Audit: CGSB auditors conduct the on-site verification audit.

Audit Outcomes: CGSB provides operator with a written audit report that includes CARs for all outstanding non-conformances. A significant number or severity of non-conformances may delay certification substantially.

Operator Follow-up: Operator provides CGSB with CAPs for all identified CARs within specified time frame. CGSB reviews plan.

Corrective action plan acceptable to CGSB.

Corrective action plan unacceptable to CGSB.

Certification achieved and Certificate of Recognition provided.

Operator failed to meet CAR response time frame.

A. How to Apply for Certification

The first step of applying for certification is to contact CGSB. For further information or to apply for *HACCP Advantage* certification, contact the *HACCP Advantage* Certification Officer:

By telephone: 1-819-956-3479
By fax: 1-819-956-5740
By email: roy.john@pwgsc.gc.ca

By mail: *HACCP Advantage* Program
Canadian General Standards Board
Place du Portage, Phase III, Floor 6B1
Gatineau, Quebec
K1A 1G6

Following this initial contact, CGSB will send you an application package with directions and forms to complete. You can expect to receive a manual and various application forms. You are obligated to read and understand the manual.

You may be asked to submit the following items in your application package:

- Letter of Intent indicating management commitment
- FSMS policy
- Identification of HACCP coordinator/team
- Checklist indicating all prerequisite program standards have been addressed
- List of products and HACCP plan groupings
- Checklist of HACCP plan forms 1–8 for each HACCP plan
- Blank copies of some sample records
- Written procedures for program maintenance including logbook methodology
- Internal audit results
- Application forms provided by CGSB.

From the materials you provide, CGSB will estimate the number of audit days, select the auditor(s) and develop their audit plan. CGSB will then schedule the audits and send you information pertaining to the audit plan, including identifying the auditors.

By submitting your application package, you are indicating that your Food Safety Management System, including the HACCP system, has been implemented and is ready for full review.

B. Document Review

CGSB auditors will review your documents to ensure that your facility is ready for auditing. During the document review, the auditors will identify any major components that are missing and need to be provided before the audit proceeds. For example, the auditors will verify that your FSMS includes a:

- Policy statement that commits to observing all applicable legal requirements
- Method for identifying all applicable laws
- Method for keeping current with changes in legal requirements
- Person designated by senior management as responsible for the FSMS.

With regards to your legal requirements, the auditors will not undertake a legal compliance audit; compliance is a daily management responsibility.

In their review, the auditors will verify that the HACCP documentation includes:

- The name of the HACCP coordinator/team leader and team members, if applicable
- A list of the products produced and how the products are grouped into HACCP plans
- Completed checklists indicating all prerequisite programs meeting the *HACCP Advantage* standards
- Completed checklists indicating the number of HACCP plan(s) with each including the eight *HACCP Advantage* forms
- Any scientific literature, research studies or background used to support decisions made regarding the HACCP system
- Written procedures for maintenance and update of the HACCP system.

The auditors will also verify that for each HACCP plan:

- Products are identified as to their respective types and uses
- Process(s) are adequately described.

C. Audit Process: On-Site Systems and Verification Audits

Once you have submitted your application to CGSB and documentation has been assessed as complete, the certification process continues to the next phase, on-site audits. Prior to the on-site audits you will need to assign a contact person to participate with the auditor(s). The most appropriate person would be the HACCP coordinator.

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If during the on-site audits, the auditor(s) identify a situation that constitutes an immediate threat to public health, the auditor(s) will notify you. You are then obligated to contact the applicable government authority immediately to discuss the nature of the threat and obtain further direction.

A general sequence of events will occur:

1. Orientation/Introductory Tour

Upon greeting the auditor(s) it would be helpful to give the auditor(s) a brief tour of your facility to help them become familiar with the facility layout and key personnel. The tour may take place before or after the opening meeting.

2. Opening Meeting

To officially begin the certification audit, the lead auditor will conduct an opening meeting. It is very important that the HACCP coordinator, key personnel and management are present at this meeting. If you have engaged the services of a consultant to assist in your HACCP implementation, his or her presence is also helpful. The auditor(s) will explain the purpose and scope of the audit during this meeting as well as the proposed timing and schedule, and make any necessary arrangements (e.g., safety requirements, interview schedules, break times).

3. Systems Audit

The systems audit is essentially the desk audit of your written programs and procedures. The auditor(s) will need sufficient workspace in a quiet area of your facility to conduct this assessment. The HACCP coordinator must be present to answer any questions from the auditor(s).

The auditor(s) will examine your written HACCP system documents. The purpose of the systems audit is to verify that each component of the *HACCP Advantage* requirements is sufficiently addressed.

The systems audit will be divided into a prerequisite program audit and HACCP plan audit.

For the prerequisite program audit the auditor(s) will verify that:

- All prerequisite program standards have been addressed.
- Control measures and monitoring procedures are adequate for each prerequisite standard.
- Appropriate documentation is in place.
- Appropriate record-keeping forms have been generated.

For the HACCP plan audit the auditor(s) will verify that:

- The written HACCP plan(s) contain all the necessary material as defined in the eight HACCP forms, as well as any supporting protocols and documents.
- All products and processes are adequately described and grouped into appropriate HACCP plans.
- All products that are produced fall under a documented HACCP plan.
- Record-keeping forms for all monitoring, corrective action and verification procedures have been developed.
- Critical limits and control measures are validated.
- Where applicable, scientific literature or other background documentation is provided to support the decisions made in the HACCP plan(s).
- For each CCP, the following basic questions are answered:
  –What are the critical limits?
  –How is monitoring performed?
  –How frequently is it done?
  –Who is responsible?
  –What are the corrective actions?
  –What records will be kept to demonstrate adherence to the program?

The auditors will note any non-conformances. If the non-conformances negatively impact the integrity of the overall HACCP system, corrective actions must be implemented and will be subjected to a second systems audit prior to proceeding with the verification audit. This means that you would need to fix the problems with the written program and the auditors will return at a later time to approve the corrective actions and conduct the on-site audit. If deficiencies are minor and do not impact the integrity of the overall HACCP system, the on-site verification audit will proceed.

4. Verification Audit

The verification audit allows the auditor(s) to confirm that your written HACCP system has been effectively implemented as written. During the verification audit, the auditor(s) will gather evidence needed to assess whether each component of your HACCP system is implemented as written, and is effective, current and reflects current operating conditions. The auditor(s) will gather evidence through physical observations of your facility and its operations, examination of records and monitoring results, and interviews with personnel responsible for each component. The auditor(s) will look for proof that your system is working as written and that all involved personnel understand their roles and are completing necessary tasks as required. The auditor(s) will also verify that records are accurately completed.

In addition, for the prerequisite program verification audit, the auditor(s) will verify that:

- The facility meets all design, construction and maintenance requirements described in the prerequisite program standards.
- The personnel responsible for prerequisite program activities are adequately trained, knowledgeable about their duties and are following the written program.

In addition, for the HACCP plan verification audit, the auditor(s) will verify that:

- The process flow diagram and plant schematic are accurate.
- The personnel responsible for CCP monitoring activities are adequately trained, are knowledgeable about their duties and are following the written program.

Throughout the verification audit the auditor(s) will make note of their findings, including documenting any non-conformances.

5. Closing Meeting

A closing meeting will be held after the auditor(s) have completed their assessment of your HACCP system. At the closing meeting the auditor(s) will inform you if a recommendation for certification will be made. You will be informed of the audit findings including all observations, minor non-conformances and major non-conformances. The closing meeting will also be an opportunity to correct any misunderstandings or misinformation. It would be beneficial for the HACCP coordinator, key HACCP personnel and management to be present at the closing meeting. This will help ensure that appropriate decisions and corrective actions are made in your audit follow-up.

D. Audit Outcomes and Follow-up

i. Audit Observations and Audit Report

During an audit the auditors determine if each of their findings have an impact on food safety. The severity of the impact is considered when the auditors categorize each of their findings as a major non-conformance, a minor non-conformance or an observation. A non-conformance indicates that an element does not meet the requirements of the *HACCP Advantage*.

Major Non-Conformance

A major non-conformance is a non-conformance that requires an acceptable modification of procedures in your HACCP system before CGSB will deem it to be in conformance with the *HACCP Advantage*. Generally, a major non-conformance puts the HACCP system at risk of failure.

Minor Non-Conformance

Minor non-conformances relate to non-conformances of less severity. Overall, the system is still effective in meeting the requirements. You must provide a response to each with the action taken or at least your intended action to correct the finding. Should a minor non-conformance not be corrected in sufficient time to determine its effectiveness before the next audit, it will automatically become a major non-conformance.

Observation

If the element being assessed is not a major or minor non-conformance, but the auditor has a remark, it is considered an observation. An observation could be an interpretation of a *HACCP Advantage* requirement or a statement of opportunity for improvement. You are not required to respond to an observation, but it is to your advantage to improve the program though these observations.

You will be officially notified of your audit results in a written audit report from CGSB. The report will detail the audit findings, identify non-conformances and indicate whether or not certification will be granted. The report will identify the CARs, formal requests for action to correct non-conformances identified during an audit.

ii. Responding to Audit Reports and CARs

You will be required to take action to correct, revise or amend the HACCP system to address the audit findings. Major and minor non-conformances will need a formal response to each CAR, usually within 30 days. The formal response may be written notification of correction of the non-conformance or a written corrective action plan (CAP) to address the non-conformance in a set period of time.

CGSB must find all corrective actions plans acceptable and will verify their effectiveness and completion in the next audit. Implementation of corrective actions for major non-conformances may be verified in a follow-up audit prior to the next regularly scheduled audit. You are responsible for providing the auditor(s) with evidence that the required corrective actions have been completed. The auditor(s) may conduct a follow-up audit to confirm this. Follow-up visits for minor non-conformances may occur during the next scheduled surveillance audit. At this time the auditor(s) will confirm that these corrective actions are adhered to and effective.

1. Response Meeting

Key HACCP personnel, including management and the HACCP team/coordinator, should meet to review each component of the audit report and decide upon appropriate and detailed CAPs for non-conformances. The CAPs should identify the actions that will be taken to correct or address the non-conformances.

2. Response to CARs

When non-conformances have been identified by auditors, you will be given a set time frame (typically 30 days) to address these. Within this time period you will need to develop a corrective action for each non-conformance. The corrective action should address or correct the occurrence. You should be able to defend the actions you have chosen. When the actions are complete, record them.

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Take the opportunity from all audit findings (internal and external audits) to focus more attention in the areas identified. Consider making changes and improvements to your HACCP system.
For example:

- Further or more focused training (e.g., using a more appropriate training method)
- New equipment (e.g., thermometer or chill tank)
- Procedure improvements (e.g., assigning a more appropriate person for a task)
- Changes to prerequisite programs (e.g., frequency of preventative maintenance)
- Changes to HACCP plan (e.g., adjusting CCPs or revised control measures).

The response to a CAR should include:

- Your identifying information
- Date of audit
- Reference to the prerequisite program standard or HACCP plan element that is not in conformance
- Reference to the audit report details of the non-conformance finding
- Action to be taken
- Who is responsible for corrective action
- Timeline for completion.

3. Appeals

You may appeal certification decisions to CGSB. CGSB has developed an appeals process as a fair and impartial method of resolving any audit disputes.

iii. *HACCP Advantage* Certificate

In order for your facility to be HACCP certified, the following conditions must be met:

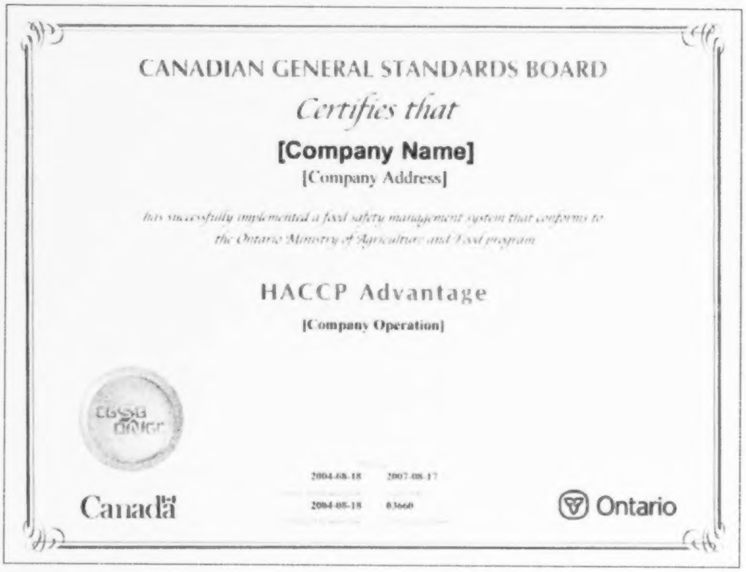
- CGSB auditors recommend your facility for certification assuming all non-conformances are addressed.
- Corrective actions for all non-conformances are submitted to CGSB for review within required timeframe.
- CGSB auditors find all corrective actions acceptable.

CGSB will notify OMAF of certified (and decertified) facilities. Certification may be withdrawn if corrective actions are not completed as scheduled.

Following successful auditing and corrective actions, you will receive a *HACCP Advantage* certificate. A sample of the certificate is provided on the next page. The certificate indicates the legal name of your company, the scope of the certification and the location of the facility as indicated in your application package. The certificate is valid for three years, provided yearly surveillance audits are successful.

Once a certificate has been granted, OMAF will provide recognition of *HACCP Advantage* certification by adding your facility to the listing of certified facilities on the OMAF *HACCP Advantage* Web site.

Figure 9.3: HACCP Advantage Certificate



CANADIAN GENERAL STANDARDS BOARD

Certifies that

[Company Name]

[Company Address]

has successfully implemented a food safety management system that conforms to the Ontario Ministry of Agriculture and Food program

HACCP Advantage

[Company Operation]

2004-08-18 2007-08-17

2004-08-18 03660

Canada

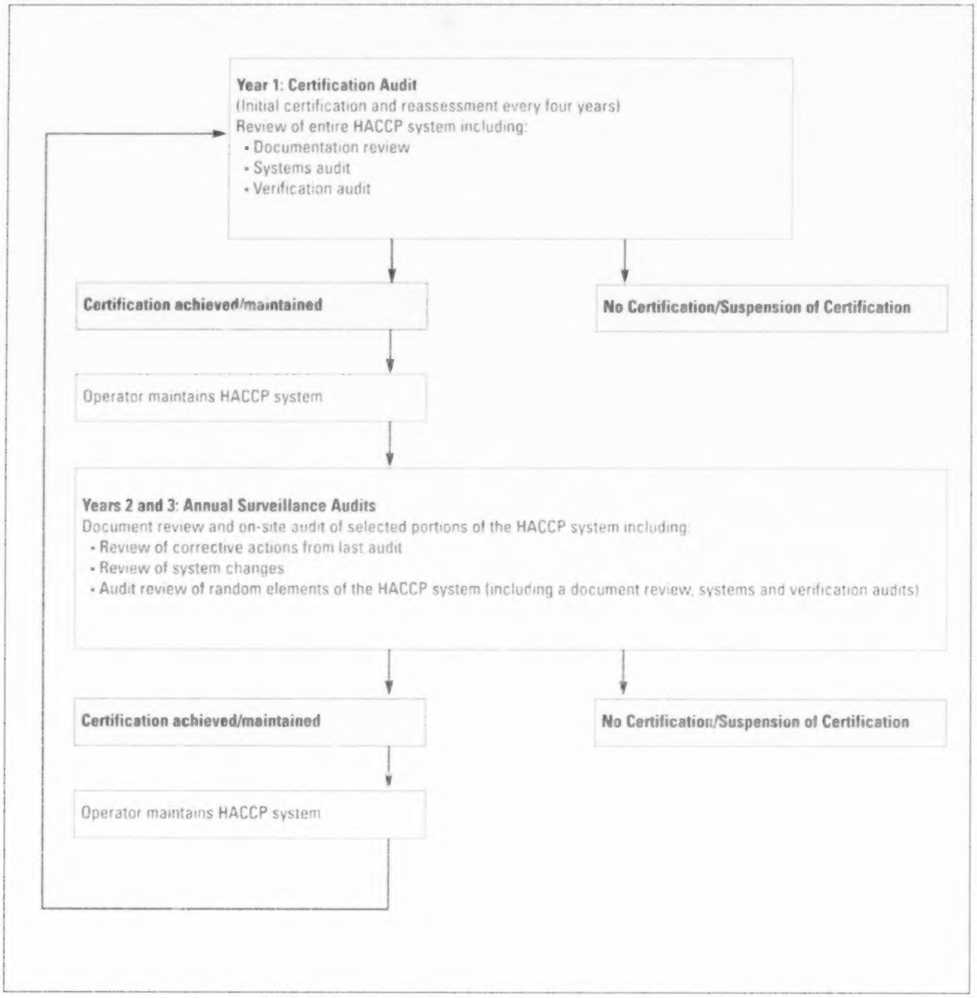
Ontario

iv. Ongoing Certification

You should keep in mind that certification is not a one-time event. To maintain your status as a certified plant you must continually maintain your HACCP system and update written programs and activities as needed.

Ongoing certification involves maintenance and updating of your FSMS, corrective action follow-up, surveillance audits and reassessments. Once you have become certified, your facility will be audited on (at least) a yearly basis. Ongoing audits are necessary to ensure that your HACCP system continues to operate effectively and allows for any changes or updates to be incorporated into your certified system. Failure to pass any audit can lead to decertification. The flow diagram below illustrates the ongoing certification process.

Figure 9.4: Flow Diagram of Ongoing Certification Process


Year 1: Certification Audit
(Initial certification and reassessment every four years)
Review of entire HACCP system including:
• Documentation review
• Systems audit
• Verification audit
Certification achieved/maintained
No Certification/Suspension of Certification
Operator maintains HACCP system
Years 2 and 3: Annual Surveillance Audits
Document review and on-site audit of selected portions of the HACCP system including:
• Review of corrective actions from last audit
• Review of system changes
• Audit review of random elements of the HACCP system (including a document review, systems and verification audits)
Certification achieved/maintained
No Certification/Suspension of Certification
Operator maintains HACCP system

v. Audit Cycle

Certification audits occur on a three-year cycle. To remain certified, your HACCP system must requalify by passing yearly audits. You will be contacted by CGSB to schedule your next audit. The audit cycle is described here.

Year 1: Full certification audit.

The full certification audit of your entire *HACCP Advantage* system includes the documentation review, systems audit and verification audit.

Year 2: Surveillance audit.

A surveillance audit includes a review of a random sample of prerequisite programs and HACCP plan CCPs as well as a review of implemented corrective actions from the previous audit and any new additions or changes to the system to ensure effectiveness.

Year 3: Surveillance audit.

The same process used in year 2 is used in year 3. Random HACCP system elements audited in year 2 will likely not be audited again in year 3.

Year 4: Full certification reassessment audit, identical to year one.

The cycle begins again in the fourth year with a full audit of the entire HACCP system, including the documentation review, systems audit and verification audit. These are conducted every three years or potentially when significant changes are made to your HACCP system. Reassessment audits are used to confirm your demonstrated commitment to maintaining your HACCP system.

vi. Your Responsibilities as an Operator for Ongoing Certification

For a facility to keep its certification, management must ensure maintenance of the FSMS as described in previous chapters. For example, you need to document compliance with changing food safety legislation and regulatory requirements, and update your HACCP system when changes are made (e.g., new HACCP plan/new CCP, new equipment or rooms, new technologies, altered product formulations).

A record or logbook of any HACCP system changes is essential for continued certification. All changes to your HACCP system must be documented in a HACCP logbook. To be considered part of the HACCP system, changes must undergo documentation review, systems audit and verification audit. It is the operator's responsibility to notify CGSB of any changes to the HACCP system that:

- Are a result of a significant process change
- Are a result of a significant change in control measures
- May directly affect food safety.

The CGSB will decide if the change warrants an immediate audit or simply an addition to the next annual surveillance audit. Failure to notify CGSB may result in the facility being decertified. Please refer to CGSB application package or contact CGSB directly for more information regarding this process.

Operators should conduct at least yearly internal audits to ensure that the HACCP system continues to effectively control food safety hazards. This internal check will help maintain the commitment and diligence of personnel to their HACCP activities. It may also highlight any gaps in a changing system as well as areas that are not being performed adequately.

vii. Suspension of Certification

Your facility's *HACCP Advantage* certification may be suspended if it fails to meet the requirements of the *HACCP Advantage*. Certification may be suspended until all non-conformances are resolved. CGSB will provide operators with written notification of suspension of certification. While certification is suspended, operators cannot claim certification in any way (for example, on signs, documents, literature or promotional materials).

Furthermore, if the non-conformances are not resolved within a time frame acceptable to CGSB, the facility will be decertified.

You can voluntarily withdraw from the certification program by requesting to be delisted if you do not wish to continue your HACCP certification and ongoing audits. Once decertified or delisted, re-certification will require starting the application process from the beginning. After decertification or delisting, operators cannot claim certification in any way (for example, on signs, documents, literature or promotional materials).

CGSB will notify OMAF of all suspended, decertified and delisted facilities, and they will be removed from the Web site listing.

4. INTERNAL AUDIT SAMPLE CHECKLISTS

Below are some sample forms you can use to complete various parts of an internal FSMS and *HACCP Advantage* audit. You should modify these forms as needed to meet the unique needs of your facility.

A. Internal FSMS Review

i. Food Safety Management System Checklist (excluding HACCP)

Objective: to confirm that the necessary components of the FSMS (excluding HACCP) are written in the FSMS protocol and are effectively implemented.

Table 9.1: FSMS Checklist Example

Check off when complete.

Requirements	
1. There is a written policy statement that commits the company to observing all applicable legal requirements.	☐
2. A method is written and followed for identifying all applicable laws.	☐
3. A method is written and followed for keeping current with changes in legal requirements.	☐
4. A person is designated by senior management as responsible for the FSMS; this person clearly understands his or her responsibilities and can demonstrate that he or she is completing his or her responsibilities.	☐
Notes (e.g., missing elements, corrective actions required):	

B. Internal Prerequisite Program Audit

i. Prerequisite Program Systems Audit

Objectives:

- To confirm that all written prerequisite programs are complete and accurate for the facility
- To confirm that the written prerequisite program policies and procedures meet the requirements of the *HACCP Advantage*
- To prepare for the certification systems audit of the prerequisite programs.

ii. Prerequisite Program Verification Audit

Objectives:

- To confirm that prerequisite program monitoring and corrective actions are conducted as written and appropriately recorded
- To prepare for the certification verification audit of the prerequisite programs.

Table 9.2 provides a sample checklist you could use to confirm that you have completed internal prerequisite program systems and verification audits. This checklist includes columns for each standard that allow you to check off that both the systems and verification audits have been completed.

Systems Audit: A systems audit typically involves reviewing your written policies and procedures to ensure completeness and accuracy.

- For each of the 57 standards ensure the following monitoring procedure information is provided:
  –What is done
  –How it is done
  –Who is responsible
  –The corrective actions
  –What records are kept.
- Ensure the written programs and procedures are complete and effective in controlling food safety hazards (based on e.g., scientific evidence, regulatory requirements, internationally accepted standards or expert determination).
- Ensure that the monitoring results and corrective actions are fully documented and are performed by the designated, trained person.
- Ensure that all records are accessible for auditor review.

Verificaton Audit: Typical activities required to complete this assessment include interviews and observations.

Some examples of systems and verification audit activities are provided below.

P7.1 Water Treatment Program

- Examine the Water Treatment Program documents to ensure that they have been reviewed at predetermined intervals.
- Ensure that the program is suitable for the facility's current operations.

T1.1 Good Manufacturing Practices Training

- Examine training materials to ensure that appropriate updates have been made.
- Examine training records to ensure that all employee training is completed as described in training schedule.

O1.3 Clothing/Footwear/Headwear

- Observe personnel to verify proper apparel.
- Inspect hair and beard coverings to verify sufficient coverage.

O6.1 Product Code/Labelling Monitoring

- Inspect labels to verify ingredients declared, instructions listed for handling/preparing/storing, and products coded according to established system.
- Examine labels in storage for clear identification.
- Examine records to verify system of dating and coding of packages is documented and included in the recall program.

E3.1 Internal Structures and Fittings

- Inspect internal structures (e.g., floors, walls, ceilings, overheads, doors, windows, stairs) checking for physical integrity and condition (e.g., no loose screws, flaking, chipping).
- Verify that floors, walls, ceilings, overheads, doors, windows, stairs and other structures are cleanable.
- Verify that maintenance schedules are followed.

E4.1 Equipment Design, Construction and Installation

- Inspect equipment for signs of degradation (e.g., cracks).
- Verify that equipment is clean, sanitized and maintained.
- Inspect for chipping, metal flakes, vibration, abrasion or pitting that could cause contamination.

Table 9.2: General Checklist for Written Prerequisite Program Policies and Procedures Example

Program Meets the Standard (57 standards)					Notes (e.g., missing elements, corrective actions required)
Prerequisite Program	**Control Programs**	**Training**	**Operational Contol**		
	Systems Audit	Systems Audit	Systems Audit	Verification Audit	
Good Manufacturing Practices	P1.1 ☐	T1.1 ☐	01.1 ☐ 01.2 ☐ 01.3 ☐ 01.4 ☐ 01.5 ☐ 01.6 ☐ 01.7 ☐ 01.8 ☐ 01.9 ☐	01.1 ☐ 01.2 ☐ 01.3 ☐ 01.4 ☐ 01.5 ☐ 01.6 ☐ 01.7 ☐ 01.8 ☐ 01.9 ☐	
Shipping, Receiving & Storage	P2.1 ☐	T2.1 ☐	02.1 ☐ 02.2 ☐ 02.3 ☐ 02.4 ☐ 02.5 ☐ 02.6 ☐ 02.7 ☐ 02.8 ☐ 02.9 ☐ 02.10 ☐	02.1 ☐ 02.2 ☐ 02.3 ☐ 02.4 ☐ 02.5 ☐ 02.6 ☐ 02.7 ☐ 02.8 ☐ 02.9 ☐ 02.10 ☐	
Sanitation	P3.1 ☐	T3.1 ☐	03.1 ☐ 03.2 ☐	03.1 ☐ 03.2 ☐	
Equipment Maintenance	P4.1 ☐	T4.1 ☐	04.1 ☐	04.1 ☐	
Pest Control	P5.1 ☐	T5.1 ☐	05.1 ☐	05.1 ☐	
Recall	P6.1 ☐	T6.1 ☐	06.1 ☐	06.1 ☐	
Water Safety	P7.1 ☐ P7.2 ☐	T7.1 ☐ T7.2 ☐	07.1 ☐ 07.2 ☐	07.1 ☐ 07.2 ☐	
Critical Control Point		T8.1 ☐			
Process Technology		T9.1 ☐			

Environmental Controls			
	Systems Audit	Verification Audit	Notes
Facility Location & Construction	E1.1 ☐	E1.1 ☐	
	E1.2 ☐	E1.2 ☐	
Facility Design	E2.1 ☐	E2.1 ☐	
	E2.2 ☐	E2.2 ☐	
Facility Interior	E3.1 ☐	E3.1 ☐	
	E3.2 ☐	E3.2 ☐	
	E3.3 ☐	E3.3 ☐	
	E3.4 ☐	E3.4 ☐	
	E3.5 ☐	E3.5 ☐	
Equipment	E4.1 ☐	E4.1 ☐	
	E4.2 ☐	E4.2 ☐	
	E4.3 ☐	E4.3 ☐	
Water Supply	E5.1 0 ☐	E5.1 ☐	

C. Internal HACCP Plan Audit

i. HACCP Plan Systems Audit checklist

Objectives:

- To confirm that the written HACCP plan(s) are complete and accurate for the facility
- To confirm that the HACCP plan(s) meet the requirements of the *HACCP Advantage*
- To prepare for the certification systems audit of the HACCP plan(s).

Table 9.3: HACCP Plan Review Checklist Example

Complete for each HACCP plan; check off when complete. Name of HACCP Plan: ____________________

Form 1: Product Description		Notes (e.g., Missing Elements, Corrective Actions Required)
☐	All individual products are identified by name in the HACCP plan. Like products are grouped in an acceptable manner.	
☐	Product type is identified (e.g., cooked, raw, fermented, processed).	
☐	Product characteristics important to ensure food safety are listed (e.g., pH, Aw). Characteristics listed are similar for all products covered by the HACCP plan.	
☐	Recipe meets the requirements of the *Food and Drugs Act.*	
☐	Label meets the requirements of the *Consumer Packaging and Labelling Act* and Regulations. Label for each product is available upon request and a sample of labels is found to be consistent with: "Product Name," "Intended Use," "Storage Instructions," and "Allergen Declaration," on the HACCP plan.	
☐	Products that contain restricted ingredients as per the *Food and Drugs Act* are declared and do not exceed acceptable levels.	
☐	Allergens as per Health Canada Guidelines are declared.	
☐	Anticipated shelf life of the product(s) under intended storage conditions is stated. ("Shelf Life" must be consistent with "Important Product Characteristics," "Safe Labelling Instructions" and "Special Distribution Controls.")	
☐	Storage instructions for the product are indicated. ("Storage Instructions" must be consistent with "Shelf Life," "Intended Use" and "Important Product Characteristics.")	
☐	HACCP plan indicates the intended use of the product. This includes a description of any special delivery instructions (e.g., temperature and humidity requirements). HACCP plan indicates where the product(s) is to be sold, e.g., restaurant, retail, institution, further processing. Any sensitive populations or target groups, e.g., senior citizen homes, hospitals, baby food, are identified on the HACCP plan. ("Intended Use" must be consistent with "Important Product Characteristics," "Shelf Life" and "Storage Instructions." Special Delivery Instructions must be consistent with "Safe Labelling Instructions.")	

Form 2: Ingredients and Incoming Materials		Notes (e.g., Missing Elements, Corrective Actions Required)
☐	All incoming raw materials and ingredients coming in contact with the product(s) or used in the preparation of the product(s) are listed.	
☐	All processing aids coming in contact with the product(s) or used in the preparation of the product(s) are listed.	
☐	All packaging materials coming in contact with the product(s) or used in the preparation of the product(s) are listed.	
☐	All hazards associated with each incoming raw material/ingredient, processing aid and packaging material are identified, including indication as B (Biological), C (Chemical) or P (Physical) in the HACCP plan.	
Form 3: Flow Diagram		
☐	HACCP plan includes a complete step-by-step flow diagram of the process.	
☐	All hazards associated with processing steps are identified as B (Biological), C (Chemical) or P (Physical) on the HACCP plan.	
☐	On-site verification is performed to confirm that the flow diagram is accurate and complete in relation to hazard identification.	
Form 4: Plant Schematic		
☐	HACCP plan includes a plant schematic of the facility and equipment used in the process. The plant schematic outlines product flow (e.g., raw versus finished) and people flow within the facility.	
☐	Plant schematic indicates points of possible cross-contamination. All hazards associated with cross-contamination are identified as B (Biological), C (Chemical) or P (Physical), in the HACCP plan.	
☐	On-site verification is performed to confirm that the plant schematic is accurate and complete in relation to hazards associated with cross-contamination from product and people flow.	

Form 5: Hazard Description and Critical Control Point Determination		
☐	All incoming materials, all processing aids, all process steps, and all potential points of cross-contamination are identified. All items identified on Form #2, Form #3 and Form #4 are listed here.	
☐	Hazards identified for each incoming material, processing aid, processing steps and all potential points of cross-contamination are specified (e.g., salmonella, antibiotic, metallic) and a description of each provided (e.g., microbial growth versus microbial contamination).	
☐	CCPs are determined by answering Form #5 questions 1–4 for each identified hazard.	
Form 6: Flow Diagram with Critical Control Points		
☐	All CCPs are identified beside the appropriate step on the flow diagram.	
Form 7: Uncontrolled Hazards		
☐	Hazards that cannot be controlled by the operator are indicated.	
☐	Methods to address each uncontrolled hazard outside the establishment are indicated.	

Form 8: HACCP Matrix The following checks must be done for each CCP.		Notes (e.g., Missing Elements, Corrective Actions Required)
Critical Limits		
☐	Critical limits are defined to maintain the CCP under control. When applicable, the critical limits meet regulatory/program requirements.	
☐	Validate that the critical limits are appropriate (e.g., sampling plan, laboratory procedures).	
Monitoring Procedures		
☐	Monitoring procedures exist for each critical limit.	
☐	Monitoring procedures are complete (who, what, when and how).	
☐	Monitoring procedures ensure that adequate control is maintained for this CCP and give information on a timely basis allowing a decision to be made on the acceptability of product.	
☐	Results of monitoring procedures are readily available for auditors to review.	
Corrective Actions		
☐	Corrective actions exist for this CCP.	
☐	Corrective actions are complete (who, what, when and how).	
☐	Corrective actions include methods to regain control of the hazard at the CCP, prevent reoccurrence and determine the disposition of affected product (i.e., product produced since the last satisfactory monitoring action).	
Verification Procedures		
☐	Verification procedures exist for this CCP.	
☐	Verification procedures are complete (who, what, when and how). Critical limits, monitoring procedures and corrective actions are appropriate to ensure food safety.	
Record Keeping		
☐	The name and location of the records to be kept for monitoring, corrective action and verification procedures are identified.	

ii. HACCP Plan Verification Checklist

Objectives:

- To confirm that for each CCP procedures are completed as described in the written HACCP plan(s)
- To prepare for the certification verification audit of the HACCP plan(s).

Figure 9.7: HACCP Plan Verification Checklist Example

Complete for each CCP. CCP# ________________

Verification Audit		Notes (e.g., Missing Elements, Corrective Actions Required)
Monitoring		
Interview the individuals responsible for monitoring procedures of this CCP to confirm:		
☐	Understanding of critical limits and the reason and importance of monitoring this CCP.	
☐	How to perform the related monitoring procedures, including record keeping.	
Examine the following to confirm:		
☐	Monitoring activities of those individuals responsible for this CCP are conducted in accordance/consistently with the written HACCP plan.	
Examine the following to confirm:		
☐	Monitoring results are being recorded.	
Corrective Actions		
Interview the individuals responsible for monitoring procedures of this CCP to confirm:		
☐	Ability to identify deviations from, reason for, and importance of corrective actions	
☐	How to perform the required corrective actions, including record keeping.	
Examine the following to confirm:		
☐	Corrective action activities of those individuals responsible for this CCP are conducted in accordance/consistently with the written HACCP plan.	
Examine the following to confirm:		
☐	Corrective actions are being taken, as needed, and recorded for this CCP.	
Verification		
Interview those individuals responsible for verification procedures of this CCP to confirm:		
☐	Understanding of the monitoring procedures and corrective actions being verified, reason and importance of verification activities.	
☐	How to perform the verification procedures, including record keeping.	
Examine the following to confirm:		
☐	Verification activities of those individuals responsible for this CCP are conducted in accordance with the written HACCP	
Examine the following to confirm:		
☐	Verification results are being recorded.	

IN SUMMARY

After reading this chapter, you should be able to provide answers to the following questions:

1. Why are audits necessary?
2. What are your roles and responsibilities for HACCP certification of your facility?
3. What is an internal audit, and why should you conduct one yearly?
4. How do you apply for certification, and what preparation is necessary for application?

Once you can thoroughly answer these questions and act upon them you will be well prepared to apply for certification of your HACCP system.

Points to remember

- Successful auditing and certification requires sufficient preparation. Good organization and thorough, accurate documentation can make the auditing process quicker and easier, and improve your chances for success.
- A self-assessment in the form of an internal audit is vital on at least a yearly basis to ensure that your HACCP system is effective and implemented as written, and continues to be so. When internal audits are thorough and any deficiencies rectified, your on-going certification audit results will improve.
- HACCP certification is an ongoing process that requires maintenance and updating of your HACCP system, corrective action follow-up and successful completion of yearly audits. Surveillance and reassessment audits are conducted to ensure your HACCP system continues to meet the requirements of the *HACCP Advantage*.

Appendices

Appendix A: The *HACCP Advantage* and other HACCP Programs

Appendix B: Frequently Asked Questions

Appendix C: Glossary

Appendix D: Contacts

The *HACCP Advantage* and other HACCP Programs

1. EXISTING HACCP SYSTEMS AND THE *HACCP ADVANTAGE*

You may have already developed and implemented an effective HACCP system. Now you wonder "Can my pre-existing HACCP system be certified under the *HACCP Advantage*?" The answer is "Yes."

If your system is already recognized under the Canadian Food Inspection Agency's (CFIA) FSEP (*Food Safety Enhancement Program*) or QMP (*Quality Management Program*), you are already realizing the benefits of HACCP recognition and likely don't need *HACCP Advantage* certification. Nevertheless, you can also apply for *HACCP Advantage* certification.

If your system is audited and verified by an independent agency and this is all that's required to meet your needs, you may choose to not apply for *HACCP Advantage* certification at this time. Remember, the *HACCP Advantage* program is voluntary—you are not required to be certified.

However, if your system is ineligible for recognition by the CFIA and you require government certification/recognition of your system, you may want to apply to CGSB for certification and recognition under the *HACCP Advantage* program.

Having your existing HACCP system certified under the *HACCP Advantage* is probably easier that you think. Since HACCP programs are based on the Codex Alimentarius HACCP principles and General Principles of Food Hygiene, you are likely already meeting many of the requirements of the *HACCP Advantage.*

If you have FSEP in place, you will notice that there are many similarities between it and the *HACCP Advantage.* This isn't a coincidence! Much of the *HACCP Advantage* is based on FSEP and was designed to have the same food safety outcomes.

If you are planning to apply to CGSB for certification and recognition of your existing HACCP system (e.g., FSEP) under the *HACCP Advantage* you should follow the step-by-step guide below to facilitate the audit process.

Step-by-step guide

A. Prerequisite Programs

1. Read the Prerequisite Program section of the *HACCP Advantage Program Manual.* Determine which *HACCP Advantage* requirements you already meet or exceed.

2. For each *HACCP Advantage* requirement that you are meeting, reference the appropriate component of your existing program. This can be done by creating a table that "maps" the two programs. For instance, list the *HACCP Advantage* requirements in one column, and then list the appropriate component of your existing program in the second column. If you have FSEP in place, you can use the reference table at the end of this appendix to compare your FSEP prerequisite programs to the *HACCP Advantage* prerequisite programs. Some of the FSEP prerequisite programs are covered by two or more *HACCP Advantage* prerequisite standards and vice versa. Therefore, you may see certain element or standard references more than once.

3. Determine which *HACCP Advantage* requirements your existing program does not meet. For those, you will have to develop new programs, policies or procedures to meet these gaps. For example, FSEP does not specifically address allergen control. However, the *HACCP Advantage* does through O1.6 Allergen Control. So if you do not have an allergen control program as part of your existing HACCP system, you will have to develop a written program for this standard.

B. HACCP Plans

1. Read the HACCP Plan Forms section of the *HACCP Advantage Program Manual.* The *HACCP Advantage* HACCP plan forms may be very similar to those of your existing HACCP system, especially if you have implemented FSEP. Remember, the number of forms you have is irrelevant; just ensure that you have all the necessary information. You may want to create another "mapping table" to reference the *HACCP Advantage* form requirements to your existing HACCP plans forms.

2. Determine which *HACCP Advantage* requirements your existing HACCP system does not meet. For those, you will have to develop new programs, policies or procedures to meet the gaps. For example, The *HACCP Advantage* Form #1 requires some additional information in comparison to FSEP Form #1. You will need to answer these additional questions:

Questions	**Yes**	**No**
Recipe meets the requirements of the *Food and Drugs Act*		
Label meets the requirements of the *Consumer Packaging and Labelling Act and Regulations*		
Product contains restricted ingredients as per *Food and Drugs Act*? If yes, list restricted ingredients.		
Does product contain allergens as per Health Canada Guidelines?		

Table A1: FSEP element and HACCP Advantage Prerequisite Program Standard Reference Map

FSEP Element	HACCP Advantage Standard	Comments
A1.1.1	E1.1	
A1.1.2	E1.2	
A2.1.1	E4.3	
A2.1.2 A2.1.3 A2.1.4 A2.1.5 A2.1.6 A2.1.7	E3.1	Floors, ceilings, windows, doors and the composition/construction of all interior structures are addressed by E3.1.
A2.4.1 A4.1.3	E3.5	Slope of floors is not specifically addressed in *HACCP Advantage*; lack of pooling water is. Liquid waste systems are also covered.
A2.1.8 A2.1.9	E2.1	Requirements for living quarters/ areas where animals are kept does not apply to the universal nature of the *HACCP Advantage*. Physical and operational separation do.
A2.2.1	E3.2	
A2.2.2	E3.3	
A2.3.1 A2.3.2 C1.1.2	E3.4	All air quality and ventilation requirements are grouped together in one standard. (Go to FSEP section C1.1.1 for A2.3.3)
A2.4.2 C1.1.3	E4.2	Waste container and utensil control are grouped together in one standard.
A2.5.1 A2.5.2	02.10	Control of inedible areas is managed through one standard in the *HACCP Advantage*.
A2.5.3	Not applicable	This element does not apply to the universal nature of the *HACCP Advantage*.
A3.1.1 A3.1.2	E2.2	
A3.2.1	A combination of: E2.1, E3.1, E5.1	No direct *HACCP Advantage* standard exists for this element, but they are addressed. (Go to FSEP section C1.1.1 for A3.2.2)
A4.1.1	P7.2, 07.2	
A4.1.2 A4.1.5 A4.1.8	P7.1, 07.1	(Go to FSEP section C1.1.1 for A4.1.4)
A4.1.6 A4.1.7	E5.1	

FSEP Element	HACCP Advantage Standard	Comments
B1.1.1	P2.1, O2.1	It is important to remember that the *HACCP Advantage* program includes a written shipping, receiving and storage program requiring written criteria that address all FSEP Shipping and Receiving elements. This standard, P2.1, is the written program requirement for these elements. The O section elements listed are the individual controls that must be monitored and controlled in the facility. If the receiving area is not physically separated from the processing area as required by FSEP (B1.1.3), sufficient interim controls must be in place to prevent contamination.
B1.1.2	P2.1, O2.2	
B1.1.3	Not applicable	
B1.2.1 B1.2.2	P2.1, O2.4	
B2.1.1 B2.1.2 B2.3.1	P2.1, O2.8	
B2.2.1	O1.8	
B2.2.2	P2.1, O2.9	
B2.2.3	O1.9	
B2.2.4	O1.8	
B2.3.2	P2.1, O2.5	
C1.1.1 A2.3.3 A3.2.2 A4.1.4	E4.1	
C1.2.1 C1.2.2	P4.1, O4.1	Preventive maintenance and calibration are grouped together.
D1.1.1	P1.1, T1.1	
D1.2.1	T2.1, T5.1, T6.1, T7.1, T7.2, T8.1	More specific training is detailed and expanded upon in the *HACCP Advantage* program.
D1.2.2	T4.1	
D1.2.3	T3.1	
D1.2.4	T9.1	
D2.1.1	O1.1, O1.2, O1.3, O1.4	
D2.1.2	O1.7	
D2.2.1 D2.2.2	O1.6	
D2.2.3	O1.5	
E1.1.1 E1.1.2	P3.1, O3.1	
E1.1.3	O3.2	
E2.1.1	P5.1, O5.1	
F1.1.1 F1.2.2	P6.1	
F1.1.2	Not applicable	This element does not apply to the universal nature of the *HACCP Advantage*.
F1.2.1	O6.1	
Not applicable	O2.6	Allergen control is not specifically addressed by FSEP
Not applicable	O2.7	Packaging is not specifically addressed by FSEP.

Frequently Asked Questions

Q1—Is the *HACCP Advantage* costly to implement and suitable only for large businesses?
A1—Through extensive research, stakeholder discussions, and in-plant testing, OMAF has developed an approach to HACCP that is feasible and practical for Ontario's small and medium-sized facilities to implement, and will maximize food safety while minimizing costs to stakeholders. Although there are costs associated with implementing HACCP, a well-designed and implemented HACCP system can actually help decrease costs in certain areas. For example, product flow bottlenecks can be identified, efficient use of sanitation chemicals monitored, and employees trained to identify potential problems before they occur. The cost will depend on the extent of the changes required in a specific facility. There are many considerations that will affect the cost. These considerations include the condition of the facility, the number of products or processes and the degree to which the facility already conforms to HACCP requirements.

Q2—Can the *HACCP Advantage* be implemented in a small facility with fewer than 10 employees?
A2—Yes, the *HACCP Advantage* was developed to be feasible for even very small facilities. Small facilities may need to be extra careful when doing a gap analysis and cost-benefit analysis before deciding to implement a HACCP system to ensure that expectations are realistic.

Q3—Will facilities be required to implement HACCP?
A3—The *HACCP Advantage* has been developed as a voluntary program. It will be up to individual facilities to assess whether the benefits of implementing the program will make it economically feasible to do so.

Q4—Why are you developing a "Made in Ontario" solution for HACCP? Why not just use the FSEP/QMP program or adapt it?
A4—We have adapted the FSEP program with the intention of making a user-friendly and feasible program for small facilities. There is international recognition that small and medium-sized food processors have special needs with respect to HACCP. They face barriers and challenges that are more difficult for them to overcome than their larger counterparts. OMAF's Manager for the Science and Advisory Unit currently co-chairs a national HACCP working group that is developing a national protocol for HACCP programs that will ensure consistency across the country.

Q5—Does the program cover abattoirs and other meat processing plants? What about dairy plants?
A5—Yes, the *HACCP Advantage* is applicable to all food processing facilities regardless of commodity processed.

Q6—Does OMAF have a staffed helpline (phone, email)?
A6—OMAF has established a *HACCP Advantage* email address (HACCP.Advantage@omaf.gov.on.ca) and a *HACCP Advantage* inquiry line: 1-888-466-2372 ext 64752.

Q7—How long will it take to implement HACCP?
A7—The time required for HACCP implementation will depend upon the condition of the facility and the extent to which HACCP requirements are already being met. Some facilities will have extensive food safety systems in place and few facility upgrades to make. Others may need more substantial preparations.

Q8—How does the *HACCP Advantage* relate to, or fit in with, regulations?
A8—The *HACCP Advantage* certification process requires facilities to be compliant with applicable food safety regulations prior to certification. However, the *HACCP Advantage* certification is a separate process from regulated inspection.

Q9—If our company is HACCP certified will we still be subjected to regulated inspection and audits in addition to the HACCP audits?
A9—The *HACCP Advantage* was developed to complement existing food safety systems, not replace them. All legislation applicable to your commodity will still have to be adhered to.

Q10—How much will it cost to get HACCP certified?
A10—There will be a modest fee for certification from the Canadian General Standards Board. For more information, please contact CGSB directly. Refer to Appendix D for contact information.

Q11—How will you ensure consistency and fairness, and how will you avoid conflict of interest with a third-party system for recognition?

A11—To ensure consistency and fairness:

- Audit criteria will be established.
- Auditors will be trained in *HACCP Advantage* standards.
- CGSB has an established auditor accreditation process in place.
- CGSB is under the oversight of Standards Council of Canada.
- The *HACCP Advantage* certification will be under the oversight of a management committee comprising CGSB, OMAF and industry.

To avoid conflict of interest:

- Specific conflict of interest provisions are in the agreement with CGSB.
- The agreement provides for complete separation of audit and consulting or other types of services.
- All auditing is under the direct oversight of CGSB.

Q12—Are there differences built into the program for different commodities (e.g., different standards, different audit criteria, different auditing frequencies)?

A12—The *HACCP Advantage* consists of generic prerequisite requirements that are applicable to all commodities and facilities. The HACCP plan portion of the *HACCP Advantage* is specific to the facility, process and product. Audit frequency and criteria are standard for all types of facilities and commodities.

Q13—Will certified facilities be listed on OMAF's Web site?

A13—OMAF will list facilities certified under the *HACCP Advantage* on its Web site after CGSB has provided confirmation of their certification status.

Q14—Is certification by CGSB the same as accreditation given by other HACCP audit and service providers (e.g., AIB, GFTC)?
A14—Other HACCP audit and service providers can be an excellent resource and provide valuable information regarding a HACCP system; however, implemented *HACCP Advantage* systems will be officially certified only through CGSB. This ensures a level of consistency, transparency and government oversight for the auditing process that will prove valuable to the program as a whole. CGSB auditors may be subcontracted from other third-party HACCP auditing firms.

Q15—What happens if there is a food-borne illness incident that involves a plant certified under the *HACCP Advantage*? Who is responsible?
A15—Plant operators are responsible for the safety of the food processed in their facility whether they implement HACCP or not. Plant operators are taking enhanced control for food safety when they implement HACCP. The results of the HACCP audit reflect the circumstances that existed at a single point in time—the day of the audit. The continued maintenance of the HACCP system to the same level of conformance is the responsibility of the plant operator. HACCP non-conformances that arise between audit activities are neither the responsibility of OMAF nor CGSB.

Q16—Will products coming into Canada be required to meet HACCP standards?
A16—Food safety requirements for imported foods fall under the jurisdiction of the Canadian Food Inspection Agency. Import requirements for various food commodities can be reviewed at http://www.inspection.gc.ca/english/toc/importe.shtml

Glossary

allergen	a substance that causes some individuals to experience an immune system response, such as an allergic reaction.
appeal	a process that allows certification applicants to investigate and possibly overturn decisions made by the certifying body.
audit	an examination of facility's HACCP system that can be conducted by internal staff or external auditors.
audit report	received from the certifying body following an audit, document that details audit results.
A_w (water activity)	the availability of water in food, for bacterial growth. It is described in relation to the AW of pure water (1.00).
biological hazard	any micro-organism or toxin produced by a micro-organism that can cause food-borne illness when ingested.
CAR (Corrective Action Request)	request given by the certifying body formally requesting corrective actions for non-conformances found during an audit.
CCP (Critical Control Point)	a point, step or procedure at which a control measure can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.
CCP decision tree	a sequence of questions used to determine where CCPs are located.
certification	the status obtained from CGSB after a successful *HACCP Advantage* certification audit.

CGSB (Canadian General Standards Board)	an organization of the Government of Canada that offers comprehensive standardization services in support of economic, regulatory, procurement, health, safety and environmental interests.
chemical hazard	any chemical agent that may cause injury or illness when ingested or inhaled.
Codex Alimentarius Commission	a commission set up by the Food and Agriculture Organization (FAO) and World Health Organization (WHO) of the United Nations to develop internationally recognized food standards, guidelines and related text such as codes of practice.
conformance	state achieved when a particular prerequisite or HACCP standard is met, including all documents and records.
consultant	a person or group of people well trained in HACCP who can be contracted to assist in the development of a facility's HACCP system.
Consumer Packaging and Labelling Act	a federal act that provides for a uniform method of labelling and packaging of consumer goods as well as prevention of fraud and deception by provision of factual label information.
corrective actions	measures taken to regain control of a hazard, to determine the disposition of affected product and to prevent a reoccurrence of the problem.
critical limit	the maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce the occurrence of a food safety hazard to an acceptable level.
cross-contamination	the physical movement, or transfer, of harmful micro-organisms, allergens, chemical contaminants, or any foreign substances from one person, object, food or place to another.
decertification	loss of certification status.

deviation	failure to meet a HACCP system requirement.
documentation review	a review of a HACCP system's documents prior to the beginning of an audit to ensure that no major components of the FSMS, the prerequisite programs or the HACCP plans are missing.
flow diagram	a systematic representation of the sequence of steps or operations used in the manufacture of a particular food.
Food and Drugs Act	a federal act that establishes regulations regarding food, drugs, cosmetics and therapeutic devices.
FSEP (Food Safety Enhancement Program)	a HACCP program administered by the Canadian Food Inspection Agency.
FSMS (Food Safety Management System)	a system to ensure compliance with all legislated food safety regulations as well as any food safety systems that the processor chooses to implement.
gap analysis	a comparison of existing food safety programs to required food safety programs. This analysis determines the improvements and program development needed in order to comply with a new food safety program.
GMP (Good Manufacturing Practices)	practices, policies and procedures that promote effective hygiene and the production of safe food.
HACCP coordinator	a person designated to oversee the development, implementation and maintenance of the HACCP system.
HACCP plan	a document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration.
HACCP principles	seven conventions that are standardized by the Codex Alimentarius Commission for the development of a HACCP plan.

HACCP team	the group of people involved in the development, implementation and maintenance of the HACCP system.
hazard analysis	the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.
immuno-compromised	individuals who may be more susceptible to food-borne illness due to a deficiency in their immune response.
logbook	a record of all changes made to the HACCP system.
major non-conformance	a type of audit finding, a non-conformance that affects the overall integrity of the HACCP system and suggests that food safety is being compromised.
management commitment	the visible support and active participation of management before, during and after HACCP implementation.
minor non-conformance	a type of audit finding, a non-conformance that does not affect the overall integrity of the HACCP system.
monitoring	the process of conducting a planned sequence of observations or measurements to determine if a prerequisite program or CCP is under control.
non-conformance	failure to meet a HACCP system requirement, as documented during an audit.
observation	a type of audit finding, a statement of fact made about a facility's HACCP system that does not indicate non-conformance but could be used to improve the system.
pathogen	a micro-organism that can cause illness or disease in humans.

pH	a way of expressing the acidity or alkalinity of substances. It is expressed on a scale from 0 to 14, where 0 is extremely acidic, 7.0 is neutral, and 14 is extremely alkaline.
physical hazard	any material in food that could cause injury or illness.
plant schematic	diagram showing where each step of the manufacturing process occurs within the facility.
prerequisite programs	the procedures that are used to ensure that the environment and other factors that are not directly related to the process or product are monitored and controlled to create conditions favourable to the production of safe food products.
processing aid	a substance used in the processing of a food product that is not present in the final product.
QMP (Quality Management Program)	a HACCP system program administered by the Canadian Food Inspection Agency, designed for federally registered fish processors.
reassessment audit	an audit that occurs every three years for review of the entire FSMS and HACCP system for completeness and effectiveness.
recognition	the status obtained from OMAF after *HACCP Advantage* certification has been granted by CGSB.
regulated commodity	a commodity area that is regulated by specific legislation (e.g., dairy by *The Milk Act*).
salinity	a measure of the salt content of a food.

surveillance audit	an annual audit that involves review of randomly chosen prerequisite programs, HACCP plan CCPs, issues from previous audits (e.g., CARs) and any changes made to the HACCP system since the last audit.
systems audit	the process of evaluating the written programs, documents and records of a facility's HACCP system to ensure its validity and completeness.
uncontrolled hazard	a hazard that cannot be controlled by a facility's HACCP system.
validation	process of obtaining evidence that the elements of the HACCP system are effective.
verification	the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.
verification audit	the process of evaluating the HACCP system in action to ensure that the programs evaluated in the systems audit are implemented and properly maintained.

Contacts

Ontario Ministry of Agriculture and Food (OMAF)
http://www.gov.on.ca/OMAFRA
This link will take you to the main home page for the Ontario Ministry of Agriculture and Food. Here you will find a wealth of information on Ontario's dynamic agri-food industry and the services and programs OMAF provides.

HACCP Advantage
http://www.gov.on.ca/OMAFRA/english/food/inspection/haccp/index.html
This link will take you to OMAF's *HACCP Advantage* home page where you will find all information available pertaining specifically to the *HACCP Advantage*.

Phone: 1-800-466-2372 ext. 64752
Email: HACCP.Advantage@omaf.gov.on.ca

Canadian General Standards Board
http://www.ongc-cgsb.gc.ca
The Canadian General Standards Board (CGSB) is the certifying body responsible for auditing and certifying food processors implementing the *HACCP Advantage*. The following is CGSB's general contact information. For *HACCP Advantage* program certification requests please use the contact information listed in chapter nine.

Phone: 1-800-665-2472
Email: ncr.cgsb-ongc@pwgsc.gc.ca